

EXHIBIT D

Ted M. Roth, M.D.

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IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: ETHICON, INC.) Master File No.
PELVIC REPAIR SYSTEM) 2:12-MD-02327
PRODUCTS LIABILITY)
LITIGATION)
_____) JOSEPH R. GOODWIN
) U.S. DISTRICT
THIS DOCUMENT RELATES TO) JUDGE
ALL WAVE 4 PLAINTIFFS)

DEPOSITION OF TED M. ROTH, M.D.

(PROLIFT+M)

DEPOSITION OF: TED M. ROTH, M.D., taken
before Lynne M. Morrison, Notary Public in and
for the State of Maine, pursuant to notice

dated March 13, 2017, at Embassy Suites Hotel,

1050 Westbrook Street, Portland, Maine, on

March 17, 2017, commencing at 10:02 a.m.

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<p>1 APPEARANCES</p> <p>2</p> <p>3 For the Plaintiffs:</p> <p>4 Andrew N. Faes, Esq.</p> <p>5 Wagstaff & Cartmell, LLP</p> <p>6 4740 Grand Avenue, Suite 300</p> <p>7 Kansas City, MO 64112</p> <p>8 (816) 701-1100</p> <p>9 afaes@wcllp.com</p> <p>10</p> <p>11 For the Defendant:</p> <p>12 Diana Katz Gerstel, Esq.</p> <p>13 Riker Danzig Scherer Hyland Perretti, LLP</p> <p>14 Headquarters Plaza</p> <p>15 One Speedwell Avenue</p> <p>16 Morristown, NJ 07962-1981</p> <p>17 (973) 451-8468</p> <p>18 dgerstel@riker.com</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p>	<p>1 TRANSCRIPT OF TESTIMONY</p> <p>2 * * * * *</p> <p>3 TED M. ROTH, M.D., having been duly sworn by the</p> <p>4 Notary Public, was deposed and testified as</p> <p>5 follows:</p> <p>6 * * * * *</p> <p>7 DIRECT EXAMINATION</p> <p>8 BY MR. FAES:</p> <p>9 Q. Good morning, Dr. Roth.</p> <p>10 A. Good morning.</p> <p>11 Q. My name is Andy Faes, and we met yesterday</p> <p>12 where we talked for about five hours regarding</p> <p>13 your opinion, general opinions on the TVT and</p> <p>14 TVT-O devices. Do you remember that?</p> <p>15 A. Yes.</p> <p>16 Q. And today we're here to talk about your</p> <p>17 general opinions regarding the Prolift+M</p> <p>18 device. Is that your understanding?</p> <p>19 A. Yes.</p> <p>20 Q. As before, as with yesterday, if I ask a</p> <p>21 question that you don't understand for any</p> <p>22 reason, please let me know and I'll try to</p> <p>23 rephrase the question. If you answer the</p> <p>24 question, I will assume that you understood</p>
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<p>1 INDEX</p> <p>2 WITNESS: TED M. ROTH, M.D.</p> <p>3 Direct Examination by Mr. Faes: 4, 92</p> <p>4 Cross-Examination by Ms. Katz Gerstel: 83, 98</p> <p>5</p> <p>6 EXHIBITS</p> <p>7 Exhibit No. Description Page</p> <p>8 1 Notice to Take Deposition of</p> <p>9 Ted Roth, M.D. 5</p> <p>10</p> <p>11 2 Defense Expert General Report of</p> <p>12 Ted Roth, M.D. 7</p> <p>13 3 Curriculum vitae 16</p> <p>14 4 "CONFIDENTIAL - SUBJECT TO STIPULATION</p> <p>15 AND ORDER OF CONFIDENTIALITY"</p> <p>16 ETH.MESH.01595614-01595619</p> <p>17 Gynecare Prolift +M IFU 54</p> <p>18</p> <p>19 5 "CONFIDENTIAL - SUBJECT TO STIPULATION</p> <p>20 AND ORDER OF CONFIDENTIALITY</p> <p>21 ETH.MESH.19580129-ETH.MESH.19580130</p> <p>22 E-mails dated May 28, 2014 and October</p> <p>23 30, 2013 73</p> <p>24</p> <p>25 *(Exhibits 1 through 5 included in original and</p> <p>26 copies.)</p> <p>27</p> <p>28</p> <p>29</p> <p>30</p> <p>31</p> <p>32</p> <p>33</p> <p>34</p>	<p>1 the question as asked. Fair enough?</p> <p>2 A. Yes.</p> <p>3 Q. Doctor, I've handed you four premarked</p> <p>4 exhibits. The first exhibit is Exhibit No. 1,</p> <p>5 which is the Notice of Deposition. It's the</p> <p>6 same notice as yesterday.</p> <p>7 Have you brought anything with you today</p> <p>8 in response to that notice that you didn't</p> <p>9 already produce yesterday?</p> <p>10 A. No.</p> <p>11 Q. Oh, and I just wanted to ask you actually one</p> <p>12 more question. Back up.</p> <p>13 Is it your understanding that you're here</p> <p>14 today -- you're only being offered as an</p> <p>15 expert this time regarding the Prolift+M</p> <p>16 device?</p> <p>17 A. That's my understanding.</p> <p>18 MR. FAES: And I just want to make it</p> <p>19 clear for the record that we've been told that</p> <p>20 at this time he's only being offered as a</p> <p>21 general expert on the Prolift+M device even</p> <p>22 though his expert report contains information</p> <p>23 on the Prolift and Gynemesh PS device as well.</p> <p>24 So if he's declared as a general expert on</p>

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<p>1 either the Prolift or Gynemesh PS at a later</p> <p>2 date, we would reserve our rights to take an</p> <p>3 additional deposition on those two products at</p> <p>4 that time. Is that your understanding as</p> <p>5 well?</p> <p>6 MS. KATZ GERSTEL: Yes, that's our</p> <p>7 understanding.</p> <p>8 BY MR. FAES:</p> <p>9 Q. So what have you brought with you today to</p> <p>10 this deposition?</p> <p>11 A. I brought a copy of my report on Prolift and</p> <p>12 Prolift+M, which you have, and I brought some</p> <p>13 selected articles from my reliance list</p> <p>14 similar to actually the one I brought</p> <p>15 yesterday but left in my bag.</p> <p>16 Q. And yesterday we marked a supplemental</p> <p>17 reliance list during your TVT and TVT-O</p> <p>18 deposition. I believe it was Exhibit 3A. Is</p> <p>19 that your reliance list for your opinions in</p> <p>20 the Prolift+M case as well?</p> <p>21 A. I can't remember what specifically was on the</p> <p>22 supplemental reliance list, but I think the</p> <p>23 reliance list is pretty much everything from</p> <p>24 TVT, TVT-O, Prolift, Prolift+M, Gynemesh PS.</p>	<p>1 contain all of the opinions that you've</p> <p>2 reached regarding the Prolift+M in this case?</p> <p>3 A. Yes.</p> <p>4 Q. Now, this particular report is titled Prolift,</p> <p>5 Prolift+M and Gynemesh PS; is that correct?</p> <p>6 A. It is.</p> <p>7 Q. So you've combined three different products</p> <p>8 into a single report; is that correct?</p> <p>9 A. Yes.</p> <p>10 Q. Do you have an understanding that the</p> <p>11 Prolift+M device has a completely different</p> <p>12 mesh than what is in the Prolift, and it's</p> <p>13 different than the Gynemesh PS?</p> <p>14 A. Yes.</p> <p>15 Q. So even though it contains a completely</p> <p>16 different mesh, you still felt it was</p> <p>17 appropriate to combine all your opinions</p> <p>18 regarding these three products into a single</p> <p>19 report?</p> <p>20 A. Yes.</p> <p>21 Q. Now, I was going through your report, and I</p> <p>22 don't see that you mention the Prolift+M</p> <p>23 specifically until about page 28 of your</p> <p>24 report. Do you know if that's accurate or</p>
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<p>1 Q. Is there any literature that you've brought</p> <p>2 with you today that isn't listed on the</p> <p>3 exhibit that we marked yesterday as Exhibit 3A</p> <p>4 which was your supplemental reliance list?</p> <p>5 A. This is all part of the reliance list, nothing</p> <p>6 different than what was on the reliance list.</p> <p>7 Q. And does the reliance list we marked yesterday</p> <p>8 as Exhibit 3A contain a listing of all the</p> <p>9 materials that you've reviewed and relied upon</p> <p>10 in forming your opinions regarding the</p> <p>11 Prolift+M product?</p> <p>12 A. Yes.</p> <p>13 Q. You brought a report with you today regarding</p> <p>14 the Prolift+M, and I've also marked a copy of</p> <p>15 that as Exhibit No. 2. Do you have that in</p> <p>16 front of you?</p> <p>17 A. Yes.</p> <p>18 Q. Is that the same report as what you've brought</p> <p>19 with you today on your own?</p> <p>20 A. It appears to be the same report, yes.</p> <p>21 Q. And this report is dated January 31, 2017. Is</p> <p>22 that when you completed and signed it?</p> <p>23 A. Yes.</p> <p>24 Q. Does this report marked as Exhibit No. 2</p>	<p>1 not?</p> <p>2 A. That's where I sort of focus on the Prolift+M</p> <p>3 in particular.</p> <p>4 Q. And I guess I don't want to belabor that</p> <p>5 point. I guess you do use Prolift+M in one</p> <p>6 other spot on page 13, but I guess what I'm</p> <p>7 getting at in my question to you is in pages 1</p> <p>8 through 27 when you're repeatedly referring to</p> <p>9 the Prolift, are you using the Prolift</p> <p>10 interchangeably with Prolift+M on pages 1</p> <p>11 through 27 of your report, or are you</p> <p>12 specifically referring to the older Prolift</p> <p>13 device which contains the Gynemesh PS mesh,</p> <p>14 not the Ultrapro mesh?</p> <p>15 A. Ultimately, it depends upon which paragraph</p> <p>16 you're referring to. For instance, page 11,</p> <p>17 paragraph marked C, so, for instance, that</p> <p>18 study is the original Prolift. Complications</p> <p>19 listed on page 12, again, I think I used the</p> <p>20 language transvaginal mesh, mesh kits, so that</p> <p>21 would include both Prolift+M and the original</p> <p>22 Prolift. Page 13, mesh exposure is a risk of</p> <p>23 transvaginal mesh, Prolift, Prolift+M,</p> <p>24 Gynemesh PS. Page 10, Altman's Randomized</p>

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<p>1 Control Trial was the original Prolift.</p> <p>2 You know, um, I mean, I certainly could</p> <p>3 have submitted three separate reports. I</p> <p>4 mean, I could have repeated a lot of</p> <p>5 information in the first part of the report</p> <p>6 for the original Prolift covering the</p> <p>7 Prolift+M. I didn't really see a need to</p> <p>8 separate out the products in a report.</p> <p>9 Q. I mean, I guess what I'm getting at, is there</p> <p>10 any spot in this report where you refer to the</p> <p>11 Prolift when you are actually referring to the</p> <p>12 Prolift and the Prolift+M as well, and how</p> <p>13 would I as a reader who is trying to</p> <p>14 understand your opinions that you're going to</p> <p>15 offer in this case know the difference, if</p> <p>16 that is, indeed, the case?</p> <p>17 A. Well, most of my opinions for the Prolift+M, I</p> <p>18 guess, start on page 28, although some of what</p> <p>19 I write about in terms of degradation of</p> <p>20 polypropylene toxicity, because the Prolift+M</p> <p>21 is also polypropylene, applies to Prolift+M.</p> <p>22 The issues with Recall Bias that I</p> <p>23 discuss on page 20 apply to not only Prolift+M</p> <p>24 and Prolift but almost all surgical</p>	<p>1 A. I mean, you have the bill or the accountable</p> <p>2 hours there. Can I review that?</p> <p>3 Q. Sure. And just for the record, you're</p> <p>4 referring to the exhibit that we marked at</p> <p>5 yesterday's deposition as Exhibit 1A.</p> <p>6 A. So specifically for the Prolift+M reports,</p> <p>7 although the original report I think that I</p> <p>8 wrote was actually Prolift and Gynemesh and</p> <p>9 then I was asked to essentially add Prolift+M</p> <p>10 to that report, I probably spent, let's see,</p> <p>11 at least 12.25 hours on the Prolift+M portion</p> <p>12 of the report. But there was also revisions</p> <p>13 made to the Prolift, Gynemesh PS part of the</p> <p>14 report. 15 or 20 hours for the Prolift+M part</p> <p>15 of the report.</p> <p>16 Q. Okay. Now, in your report, you discuss both</p> <p>17 Gynemesh PS and Prolift. Do you have an</p> <p>18 understanding that the mesh in the -- that the</p> <p>19 Gynemesh PS is the same mesh as what is in the</p> <p>20 Prolift mesh?</p> <p>21 A. Yes.</p> <p>22 Q. And what is your understanding with regard to</p> <p>23 the Prolift+M mesh? Do you know if that mesh</p> <p>24 is used for any other application?</p>
Page 11	Page 13
<p>1 procedures. Biocompatibility of Polypropylene</p> <p>2 mesh, page 21, would apply to the</p> <p>3 polypropylene that is both in Prolift and</p> <p>4 Gynemesh PS and Prolift+M. Discussion of</p> <p>5 infection, page 16, regarding Type I</p> <p>6 macroporous meshes would apply to both</p> <p>7 Prolift, Gynemesh and Prolift+M.</p> <p>8 So I didn't mean to make it confusing in</p> <p>9 terms of addressing the individual products.</p> <p>10 I just tried to because brevity is the soul of</p> <p>11 wit combine a report for all three products.</p> <p>12 Q. And how many -- well, strike that.</p> <p>13 When were you first approached to be an</p> <p>14 expert specifically regarding the Prolift+M</p> <p>15 product?</p> <p>16 A. It was the same time that I was approached to</p> <p>17 be an expert for TVT, and we chatted about</p> <p>18 that yesterday. My recollection is I was</p> <p>19 contacted by Doug DiPaola 2014, 2015ish.</p> <p>20 Q. And how many hours would you say you've spent</p> <p>21 working on your Prolift+M report, and that</p> <p>22 includes both review of materials and writing</p> <p>23 the actual report as well as any deposition</p> <p>24 prep time?</p>	<p>1 A. My understanding is that the other name for</p> <p>2 the Prolift+M, I don't know if it's still</p> <p>3 marketed as such, is the Ultrapro mesh, and I</p> <p>4 think that has applications in hernia repair.</p> <p>5 Q. So you would agree that the Prolift+M mesh is</p> <p>6 still available as the Ultrapro mesh for sale</p> <p>7 to physicians for use in the United States,</p> <p>8 correct?</p> <p>9 A. Um, I'm not too sure. I don't do abdominal</p> <p>10 hernia repairs, and I haven't investigated</p> <p>11 whether Ultrapro is still marketed or</p> <p>12 available.</p> <p>13 Q. Okay. In your expert report marked as Exhibit</p> <p>14 No. 2, you go through various facts and</p> <p>15 literature and discuss various facts and</p> <p>16 literature. Did you discuss the facts and</p> <p>17 literature in your expert report that you felt</p> <p>18 were the most important to you in drawing your</p> <p>19 conclusions and making your opinions regarding</p> <p>20 the Prolift+M device?</p> <p>21 A. Yes.</p> <p>22 Q. And there are also, as I said, articles cited</p> <p>23 throughout your report, correct?</p> <p>24 A. There is articles cited for Prolift+M, and</p>

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<p>1 there is articles cited for Prolift and</p> <p>2 polypropylene, yes.</p> <p>3 Q. In terms of your decision-making in writing</p> <p>4 your report, why did you cite the articles</p> <p>5 that you did in your report with regard to</p> <p>6 Prolift+M?</p> <p>7 A. Do you want me to go through each article and</p> <p>8 their merits?</p> <p>9 Q. Well, I was more asking a general question of</p> <p>10 why you chose the articles that you did to</p> <p>11 discuss in your report.</p> <p>12 A. I tried to carefully review the literature.</p> <p>13 These were, in my opinion, the salient</p> <p>14 articles on Prolift+M. That's why I chose</p> <p>15 these articles.</p> <p>16 Q. Would you agree that they're the articles --</p> <p>17 strike that.</p> <p>18 You'd agree that the articles that you</p> <p>19 cited -- specifically cited in your report is</p> <p>20 not a comprehensive listing of all the</p> <p>21 available medical literature specifically</p> <p>22 regarding the Prolift+M, correct?</p> <p>23 A. I don't know that I can tell you how many</p> <p>24 actual articles are out there for Prolift+M.</p>	<p>1 Then there was also a reference made to</p> <p>2 an article on the hernia literature about</p> <p>3 heavyweight, mid-weight, lightweight</p> <p>4 polypropylene meshes. Then there was</p> <p>5 Quemener, which has a slightly different study</p> <p>6 design but also had a follow-up with 20 months</p> <p>7 with a fairly significant number of patients.</p> <p>8 Another retrospective cohort study by Lensen</p> <p>9 looking at both patients with Prolift and</p> <p>10 Prolift+M combined.</p> <p>11 I felt like these were the key articles.</p> <p>12 I also like the article by Body which looked</p> <p>13 at sexual function after patients with Prolift</p> <p>14 and Prolift+M. And, ultimately, you know,</p> <p>15 because there is not really a lot of</p> <p>16 randomized control trials of Prolift+M, I did</p> <p>17 cite one of the meta-analyses or actually</p> <p>18 multiple meta-analyses, which, again, is the</p> <p>19 best evidence -- much better evidence for than</p> <p>20 cohort studies or RCTs.</p> <p>21 I don't know if that answers your</p> <p>22 question.</p> <p>23 Q. I think so, Doctor. I've re-marked a copy of</p> <p>24 your C.V. from yesterday as Exhibit No. 3.</p>
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<p>1 Q. Yeah, I understand, Doctor. My question is</p> <p>2 you would agree that you didn't -- I think</p> <p>3 that's a fairly non-controversial question.</p> <p>4 You didn't choose to cite every single article</p> <p>5 that is available regarding Prolift+M in the</p> <p>6 body of your report, correct?</p> <p>7 A. Yeah, correct.</p> <p>8 Q. So you said that you chose what you felt were</p> <p>9 the most salient ones, right?</p> <p>10 A. That's correct.</p> <p>11 Q. So my question is what about the articles you</p> <p>12 chose led you to believe that they were the</p> <p>13 most salient articles, in your words?</p> <p>14 A. So I guess I can ask again, do you want me to</p> <p>15 go through each one of the articles that I</p> <p>16 reviewed and describe why I think each one has</p> <p>17 merit and is salient because it's kind of a</p> <p>18 broad question?</p> <p>19 Each of the articles that I used are</p> <p>20 certainly different. You have Khandwala's</p> <p>21 article. That's a prospective cohort, single</p> <p>22 center. You have Milani. That's a cohort</p> <p>23 study but multiple centers also with one year</p> <p>24 follow-up as well Khandwala's study.</p>	<p>1 A. Sure.</p> <p>2 Q. If you need to refer back to that, you can.</p> <p>3 But within your C.V. there is a list of</p> <p>4 publications. Do any of the publications in</p> <p>5 your C.V. specifically address the Prolift+M</p> <p>6 device?</p> <p>7 A. No, not specifically, no.</p> <p>8 Q. Do any of the publications on your C.V. that</p> <p>9 you've participated in address the</p> <p>10 transvaginal mesh technique for the treatment</p> <p>11 of prolapse?</p> <p>12 A. The only publication -- well, I did a book</p> <p>13 chapter on vaginal stricture after pelvic</p> <p>14 organ prolapse surgery, and some of that</p> <p>15 chapter covers mesh revision surgery and those</p> <p>16 challenges.</p> <p>17 Q. Are there any other publications that you've</p> <p>18 done that specifically address the TVM</p> <p>19 technique for the treatment of prolapse?</p> <p>20 A. No.</p> <p>21 Q. Would you agree that the Prolift+M is an</p> <p>22 alternative surgical procedure for the</p> <p>23 treatment of prolapse as compared to other</p> <p>24 techniques that are available to physicians?</p>

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<p>1 MS. KATZ GERSTEL: Object to form.</p> <p>2 A. I mean, it's available in the armamentarium,</p> <p>3 or it was available in a surgeon's</p> <p>4 armamentarium for prolapse, so it's an</p> <p>5 alternate to traditional methods.</p> <p>6 BY MR. FAES:</p> <p>7 Q. Now, you've used both the Prolift and the</p> <p>8 Prolift+M in your practice, correct?</p> <p>9 A. That's correct.</p> <p>10 Q. And you've implanted approximately 160</p> <p>11 Prolifts and 80 Prolift+Ms; is that correct?</p> <p>12 A. That's about right.</p> <p>13 Q. How many -- strike that.</p> <p>14 When was the first time that you</p> <p>15 implanted a Prolift device, the original</p> <p>16 Prolift?</p> <p>17 A. 2005, 2006, maybe.</p> <p>18 Q. And when was the first time that you implanted</p> <p>19 the Prolift+M device?</p> <p>20 A. It was probably sometime in 2008, late 2008, I</p> <p>21 think.</p> <p>22 Q. So you believe that you first implanted the</p> <p>23 Prolift+M device in late 2008?</p> <p>24 A. I think so.</p>	<p>1 prior to and during surgery between the</p> <p>2 Prolift and the Prolift+M mesh?</p> <p>3 MS. KATZ GERSTEL: Object to form.</p> <p>4 A. Yes.</p> <p>5 BY MR. FAES:</p> <p>6 Q. Do you have to -- do you feel like you have to</p> <p>7 handle the mesh any differently during</p> <p>8 implantation of the device?</p> <p>9 A. I think what you mean is how you tension the</p> <p>10 mesh or how you place the mesh, is that</p> <p>11 different during the procedure because of how</p> <p>12 the meshes feel in your hand?</p> <p>13 Q. Yes.</p> <p>14 A. Yes.</p> <p>15 Q. How is it different?</p> <p>16 A. So the Prolift+M at least, you know, in your</p> <p>17 hand is a little stiffer than the original</p> <p>18 Prolift, and I would attribute that to the</p> <p>19 weight of the mesh because of the combination</p> <p>20 of the polypropylene and the Monocryl, the</p> <p>21 dissolvable material.</p> <p>22 Q. Did any -- strike that.</p> <p>23 Do you feel like you have to handle the</p> <p>24 Prolift+M mesh differently when you place it</p>
Page 19	Page 21
<p>1 Q. Were you specifically trained on the Prolift+M</p> <p>2 device, or did you just rely on your previous</p> <p>3 training on the Prolift device before you</p> <p>4 implanted that the first time?</p> <p>5 A. There was not really significant -- I wouldn't</p> <p>6 really consider it significant changes to the</p> <p>7 device. Means of introduction, trocars,</p> <p>8 essentially it was the same technique. So as</p> <p>9 far as I know, there wasn't additional or</p> <p>10 supplemental training offer.</p> <p>11 Q. Prior to using the Prolift+M for the first</p> <p>12 time, did anyone instruct you or inform you</p> <p>13 that the handling of the mesh could be</p> <p>14 different?</p> <p>15 MS. KATZ GERSTEL: Object to form.</p> <p>16 A. Handling of the mesh? I'm not sure what you</p> <p>17 mean.</p> <p>18 BY MR. FAES:</p> <p>19 Q. Let me back up. First of all, you've held</p> <p>20 both the Prolift mesh and the Prolift+M mesh</p> <p>21 in your hands prior to and during surgery,</p> <p>22 right?</p> <p>23 A. Yes.</p> <p>24 Q. Does the mesh feel different in your hands</p>	<p>1 in order for the mesh to be placed</p> <p>2 successfully compared to the Prolift</p> <p>3 procedure?</p> <p>4 MS. KATZ GERSTEL: Object to form.</p> <p>5 A. No, I don't think that the technique was all</p> <p>6 that different. It was you still have to</p> <p>7 place the mesh in a, as they say, a tension-</p> <p>8 free fashion, lay the mesh in flat, you know,</p> <p>9 secure the mesh, or at least my inclination</p> <p>10 was to secure the mesh at the bladder neck and</p> <p>11 also secure the mesh at the cervix, really not</p> <p>12 all that significant.</p> <p>13 BY MR. FAES:</p> <p>14 Q. When you first started using the Prolift+M</p> <p>15 mesh in 2008, did you have an understanding at</p> <p>16 that time that you were one of the first</p> <p>17 physicians in the United States to start using</p> <p>18 that device?</p> <p>19 A. I think I was one of the first physicians to</p> <p>20 use the original Prolift, too. Yeah, I think</p> <p>21 that the Prolift+M was cleared by the FDA</p> <p>22 sometime in maybe May of 2008. But, like I</p> <p>23 said, to the best of my recollection, I</p> <p>24 probably used it in late 2008 or 2009.</p>

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<p>1 Q. Did you have an understanding when you were</p> <p>2 using the Prolift+M in 2008 and 2009 that</p> <p>3 Ethicon and Johnson & Johnson hadn't made the</p> <p>4 Prolift+M available to all surgeons; they kind</p> <p>5 of just made it available to a limited number</p> <p>6 of surgeons? Did you have that understanding</p> <p>7 or not?</p> <p>8 A. I don't know that that was made clear to me.</p> <p>9 Q. Do you know whether or not that's true today?</p> <p>10 A. I haven't investigated who got their hands on</p> <p>11 Prolift+M sooner than other folks.</p> <p>12 Q. So in forming your opinions in this case, you</p> <p>13 don't know when Ethicon and Johnson & Johnson</p> <p>14 did what they called a full launch of the</p> <p>15 Prolift+M device, meaning they made it</p> <p>16 generally available to all physicians as</p> <p>17 opposed to just selected physicians?</p> <p>18 A. I don't know.</p> <p>19 Q. And you were a preceptor for Prolift+M,</p> <p>20 correct?</p> <p>21 A. I was a preceptor or proctor for both Prolift</p> <p>22 and Prolift+M.</p> <p>23 Q. Can you recall -- strike that.</p> <p>24 When was the first time that you did a</p>	<p>1 that, do you feel that would be an appropriate</p> <p>2 action by Ethicon and Johnson & Johnson?</p> <p>3 MS. KATZ GERSTEL: Object to form.</p> <p>4 A. I don't know what you mean by appropriate.</p> <p>5 You know, I didn't have qualms about training</p> <p>6 people on Prolift+M or training them on the</p> <p>7 original Prolift.</p> <p>8 Q. So you don't think it would be inappropriate</p> <p>9 for a medical device company to say if you're</p> <p>10 going to continue to be a teacher for device A</p> <p>11 such as the Prolift, you also need to be</p> <p>12 willing and able to be a teacher on device B,</p> <p>13 the Prolift+M, whether or not you're</p> <p>14 comfortable implanting that device or not?</p> <p>15 MS. KATZ GERSTEL: Object to form.</p> <p>16 BY MR. FAES:</p> <p>17 Q. Do you think that's appropriate or not?</p> <p>18 A. I don't know that I'm in a position to judge</p> <p>19 what's appropriate for a device company since</p> <p>20 I didn't work for or at that level in a device</p> <p>21 company.</p> <p>22 Q. Well, what about as a physician, as a</p> <p>23 physician you were told that in order to</p> <p>24 continue teaching for a particular device that</p>
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<p>1 proctoring or preceptoring event specifically</p> <p>2 for the Prolift+M device, not the Prolift</p> <p>3 device?</p> <p>4 A. I have no recollection.</p> <p>5 Q. Did there come a time when Ethicon and Johnson</p> <p>6 & Johnson informed you as a proctor or</p> <p>7 preceptor that if you were going to proctor or</p> <p>8 preceptor the Prolift device that you needed</p> <p>9 to be able and willing to proctor or preceptor</p> <p>10 the Prolift+M device as well?</p> <p>11 A. I'm sorry, could you repeat that?</p> <p>12 Q. Yeah, maybe I can make it a little bit</p> <p>13 simpler.</p> <p>14 Did anyone at Ethicon and Johnson &</p> <p>15 Johnson ever tell you at some point that if</p> <p>16 you were going to be a -- continue to be a</p> <p>17 proctor or preceptor for the original Prolift</p> <p>18 device that you needed to be willing and able</p> <p>19 to proctor or be a preceptor for the Prolift+M</p> <p>20 device as well?</p> <p>21 MS. KATZ GERSTEL: Object to form.</p> <p>22 A. I don't have any recollection of that.</p> <p>23 BY MR. FAES:</p> <p>24 Q. If that was indeed the case that you were told</p>	<p>1 you also needed to be able to teach on a</p> <p>2 similar but different device regardless of</p> <p>3 whether or not you were comfortable implanting</p> <p>4 that device yourself regardless of whether or</p> <p>5 not that was your device of choice?</p> <p>6 MS. KATZ GERSTEL: Object to form.</p> <p>7 A. This is kind of hypothetical. I was</p> <p>8 comfortable with the original Prolift and</p> <p>9 comfortable with Prolift+M. I don't think</p> <p>10 that I was ever asked to or put in a situation</p> <p>11 where, you know, I had to be able to train</p> <p>12 people on both or not at all.</p> <p>13 BY MR. FAES:</p> <p>14 Q. Yeah. And it is hypothetical, and</p> <p>15 hypothetical questions are allowed. So</p> <p>16 hypothetically, if you were not comfortable</p> <p>17 with the second device that the company told</p> <p>18 you -- a company told you that you needed to</p> <p>19 be willing to teach even though you weren't</p> <p>20 comfortable implanting that device yourself or</p> <p>21 recommending it, do you think that would be</p> <p>22 appropriate?</p> <p>23 MS. KATZ GERSTEL: Object to form.</p> <p>24 A. I don't know because I was comfortable with</p>

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<p>1 both devices. I don't know that I have an</p> <p>2 opinion about that.</p> <p>3 BY MR. FAES:</p> <p>4 Q. So you don't have an opinion as a physician</p> <p>5 one way or the other of whether it would be</p> <p>6 appropriate or inappropriate for a device</p> <p>7 company to tell you that you had to be willing</p> <p>8 to teach on a similar but different device to</p> <p>9 a device that you were comfortable implanting</p> <p>10 regardless of whether or not you were</p> <p>11 comfortable with the second device?</p> <p>12 MS. KATZ GERSTEL: Objection. Asked and</p> <p>13 answered.</p> <p>14 A. Again, I was comfortable with both devices. I</p> <p>15 don't know how to answer your question.</p> <p>16 BY MR. FAES:</p> <p>17 Q. Okay.</p> <p>18 A. Sorry.</p> <p>19 Q. So when you began to start -- let me back up.</p> <p>20 When was the last time that you implanted</p> <p>21 a Prolift, the traditional Prolift device?</p> <p>22 A. I don't recall. I have a better recollection</p> <p>23 of when I probably implanted the last</p> <p>24 Prolift+M. I can give you that information.</p>	<p>1 So to answer your question, no, I have</p> <p>2 not had a patient wanting a mesh kit since</p> <p>3 2011.</p> <p>4 BY MR. FAES:</p> <p>5 Q. And specifically since July of 2011, correct?</p> <p>6 A. Thereabouts.</p> <p>7 Q. When you began to use the Prolift+M device in</p> <p>8 the latter half of 2008, did you continue to</p> <p>9 use the original Prolift device, or did you</p> <p>10 completely switch over to the Prolift+M</p> <p>11 device?</p> <p>12 A. I don't have a great recollection of sort of</p> <p>13 what we did. I think there were probably a</p> <p>14 number of Prolifts, the original Prolifts that</p> <p>15 were stocked at the hospital, and I think that</p> <p>16 we continued to use a combination of Prolift+M</p> <p>17 and the original Prolift. And then once I</p> <p>18 started seeing patients back post-operatively</p> <p>19 with the Prolift+M, I think that we stopped</p> <p>20 ordering the original Prolift and continued</p> <p>21 with the Prolift+M.</p> <p>22 Q. So you would agree that at a certain point the</p> <p>23 Prolift+M device became your kit of choice for</p> <p>24 the treatment of pelvic organ prolapse over</p>
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<p>1 Q. So that's going to be my next question, but</p> <p>2 before I move on to that, is the answer to my</p> <p>3 question of when you last implanted a</p> <p>4 traditional Prolift device is that you don't</p> <p>5 know?</p> <p>6 A. I don't know.</p> <p>7 Q. And when was the last time that you implanted</p> <p>8 a Prolift+M device?</p> <p>9 A. It was spring or summer of 2011.</p> <p>10 Q. And you would agree that you haven't had --</p> <p>11 one of the reasons that you haven't implanted</p> <p>12 a mesh kit for the treatment of pelvic organ</p> <p>13 prolapse since approximately July of 2011 is</p> <p>14 because you haven't had a patient who has</p> <p>15 wanted one since then, correct?</p> <p>16 MS. KATZ GERSTEL: Object to form.</p> <p>17 A. I think there are a few reasons why I haven't</p> <p>18 done a transvaginal mesh kit since that time.</p> <p>19 One reason is the Prolift products were</p> <p>20 removed from the marketplace and no longer</p> <p>21 available. Number two, in counseling patients</p> <p>22 about other mesh products available, a lot of</p> <p>23 them were peppered by TV advertising about</p> <p>24 litigation, you know, for mesh.</p>	<p>1 the original Prolift kit; is that accurate?</p> <p>2 A. Yes.</p> <p>3 Q. And why is that?</p> <p>4 A. Um, well, I guess I like the idea of the</p> <p>5 hybrid material. I like the idea of the</p> <p>6 increase in the pore size. The way I sort of</p> <p>7 thought about the Prolift+M was that once the</p> <p>8 absorbable Monocryl material went away, you</p> <p>9 were left with an lacier framework, if you</p> <p>10 will, of the polypropylene.</p> <p>11 The idea that using, you know, less mesh</p> <p>12 and having similar outcomes appealed to me</p> <p>13 most like -- not unlike other things in</p> <p>14 medicine where, you know, you try to use the</p> <p>15 least amount of something to achieve, you</p> <p>16 know, your goal; for instance, the lowest dose</p> <p>17 of a statin drug to control your cholesterol,</p> <p>18 et cetera. So that was part of the appeal.</p> <p>19 Q. So you testified that one of the reasons why</p> <p>20 you ultimately switched to the Prolift+M kit</p> <p>21 as your prolapse kit of choice was that you</p> <p>22 liked the idea of an increase in pore size; is</p> <p>23 that accurate?</p> <p>24 A. Yes.</p>

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<p>1 Q. So you would agree that all things being 2 equal, a lighter weight, larger pore mesh may 3 be more beneficial to a patient than a 4 heavier, smaller pore mesh, correct? 5 MS. KATZ GERSTEL: Objection, 6 mischaracterization. 7 A. I think in sort of my reading and my takeaway 8 from the literature, you know, I don't think 9 it's so much about it has to do with the 10 weight of the mesh. I think it has to do with 11 the pore size, and it doesn't always -- you 12 know, it's not always an association lighter 13 weight equals larger pores. And so for me, it 14 has to do more with the pore size than the 15 actual weight or density of the mesh material. 16 BY MR. FAES: 17 Q. Well, you've agreed that you've already 18 offered the opinion that the Gynemesh PS, 19 which is the same as the Prolift mesh, is 20 already a Type I macroporous mesh, correct? 21 A. Correct. 22 Q. And you also believe that the TVT mesh is a 23 Type I macroporous mesh, correct? 24 A. Mm-hmm.</p>	<p>1 Q. Have you ever used the PROLENE Soft mesh in 2 your medical practice? 3 A. I don't know that I can make a huge big 4 difference between PROLENE Soft and the 5 Gynemesh PS. I'm more familiar with the 6 labeling of the Gynemesh PS than PROLENE Soft. 7 Q. Do you know whether there is any difference at 8 all between the Gynemesh PS and the PROLENE 9 Soft mesh? 10 A. I'm not aware. 11 Q. Assuming that the Gynemesh PS and the PROLENE 12 Soft mesh are, in fact, exactly the same mesh, 13 do you think it's appropriate for Ethicon and 14 Johnson & Johnson to charge a substantially 15 higher price for the Gynemesh PS mesh than 16 they do for the PROLENE Soft mesh? 17 MS. KATZ GERSTEL: Objection. 18 A. You know, I'm not in R & D or marketing. I 19 don't know -- I couldn't tell you what their 20 charges were on these materials when we were 21 using them. 22 Q. Now, you stated that you've used both the 23 Gynemesh PS in your medical practice both for 24 abdominal sacrocolpopexies and for</p>
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<p>1 Q. So if both of those meshes are already Type I 2 macroporous mesh, why did you like the idea of 3 an increase in pore size with the Ultrapro 4 mesh? Did you believe that that provided your 5 patients with some additional clinical benefit 6 or not? 7 MS. KATZ GERSTEL: Object to form. 8 A. You know, again, in my understanding of the 9 literature and healing processes with mesh, at 10 least in, like I said, my understanding, the 11 appealing thing about larger pore size is how 12 the body may react to the larger pores in 13 terms of healing and fibrosis and that you 14 might have a more favorable means of healing 15 with the larger pore size than with smaller 16 pore sizes or with the mesh fibers being 17 closer together. 18 BY MR. FAES: 19 Q. And when did you first use Gynemesh PS in your 20 medical practice for the treatment of pelvic 21 organ prolapse? 22 A. Probably, I mean, I used Gynemesh PS for both 23 vaginal or transvaginal applications as well 24 as sacrocolpopexies. Probably 2005.</p>	<p>1 transvaginal mesh applications; is that 2 correct? 3 A. Yes. 4 Q. And just for the record, for the rest of the 5 day I will refer to abdominal sacrocolpopexy 6 as ASC because I don't like saying that word. 7 Do you still use the Gynemesh PS mesh for 8 transvaginal use today? 9 A. I do not. 10 Q. When did you stop using it for transvaginal 11 use? 12 MS. KATZ GERSTEL: Just place an 13 objection. This is a +M deposition. 14 MR. FAES: Objection is noted. 15 A. Probably have not used any sort of 16 polypropylene mesh transvaginally placed since 17 2011. 18 BY MR. FAES: 19 Q. And why is that? 20 A. For the reasons that we discussed earlier, 21 apart from the fact that I don't even know if 22 Gynemesh is still available, number one. And 23 two is the mesh litigation. 24 Earlier, you asked what my reasons were</p>

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<p>1 for not using Prolift+M or Prolift, and we</p> <p>2 discussed the mesh litigation and the</p> <p>3 availability of Prolift. So in regards to</p> <p>4 Gynemesh, I don't know if it's still available</p> <p>5 or being marketed, but the patients, again,</p> <p>6 are very peppered by the advertisements that</p> <p>7 they're seeing on TV regarding mesh and mesh</p> <p>8 litigation.</p> <p>9 Q. I guess my reaction, Doctor, which isn't</p> <p>10 reflected on the record, was I was under the</p> <p>11 impression that you were still using Gynemesh</p> <p>12 PS in ASC repairs; is that not accurate?</p> <p>13 A. I think you asked about transvaginal</p> <p>14 application, but for ASCs we're using a</p> <p>15 different product which is still</p> <p>16 polypropylene. And part of the theme of</p> <p>17 yesterday's deposition was cost savings.</p> <p>18 We're using a product from a different</p> <p>19 company, Caldera.</p> <p>20 Q. And what is that product that you're using?</p> <p>21 A. It's a Y-mesh, and it's called IntePro,</p> <p>22 I-N-T-E-P-R-O.</p> <p>23 Q. Actually, I'm not sure if that's right because</p> <p>24 I'm 99 percent sure that IntePro is made by</p>	<p>1 and handling characteristics and ease of</p> <p>2 suture placement, things like that.</p> <p>3 Q. Well, you'd agree that if you did believe that</p> <p>4 the Gynemesh PS mesh was the best mesh</p> <p>5 available for ASC repairs and that it would</p> <p>6 compromise patient outcomes and safety not to</p> <p>7 have that mesh available, you would go to your</p> <p>8 hospital and insist that that be made</p> <p>9 available for use in your patients; is that</p> <p>10 accurate?</p> <p>11 MS. KATZ GERSTEL: Object to form.</p> <p>12 A. Yeah, I try to be a good patient advocate; and</p> <p>13 so regardless of cost, if I felt like one mesh</p> <p>14 was better than all the other meshes in</p> <p>15 regards to safety and rate of exposure and</p> <p>16 success, then I would go to bat for that mesh.</p> <p>17 And more importantly, I would go to bat for my</p> <p>18 patients.</p> <p>19 BY MR. FAES:</p> <p>20 Q. And you haven't done that with regards to the</p> <p>21 Gynemesh PS mesh, correct?</p> <p>22 A. I have not.</p> <p>23 Q. Have you ever used the Gynemesh -- strike</p> <p>24 that.</p>
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<p>1 ASTORA Women's Health.</p> <p>2 A. What is the name of their mesh?</p> <p>3 Q. Well, I mean, just so the record is clear, you</p> <p>4 might not have the name correct, but you're</p> <p>5 fairly confident that the Y-mesh that you're</p> <p>6 using is the Caldera Y-mesh; is that accurate?</p> <p>7 A. It's actually the Caldera mesh, just the name</p> <p>8 escapes me.</p> <p>9 Q. And when did you stop using Gynemesh PS for</p> <p>10 ASC repairs?</p> <p>11 A. I don't have a specific recollection. I've</p> <p>12 used a lot of different meshes for ASC</p> <p>13 repairs, and a lot of what it sort of boiled</p> <p>14 down to was cost.</p> <p>15 Q. Do you feel that Gynemesh PS is the best mesh</p> <p>16 available for ASC repairs or not?</p> <p>17 A. I'm not aware of a specific study with ASCs</p> <p>18 that sort of touts what is the best brand of</p> <p>19 mesh. The majority of us doing ASCs are using</p> <p>20 some form of polypropylene. I think that most</p> <p>21 people would agree that polypropylene is the</p> <p>22 mesh of choice for ASCs. What brand I think</p> <p>23 has to do with perhaps how you're doing it and</p> <p>24 what your own experience with that material is</p>	<p>1 Have you ever used the Prolift+M mesh for</p> <p>2 an ASC repair? And when I say Prolift+M mesh,</p> <p>3 I am also referring to the Ultrapro mesh.</p> <p>4 A. I have not.</p> <p>5 Q. So even though at one time you felt the</p> <p>6 Ultrapro mesh was your -- strike that.</p> <p>7 So even though at one time the Prolift+M</p> <p>8 mesh, which is also the Ultrapro, was your</p> <p>9 mesh or kit of choice for the treatment of</p> <p>10 pelvic organ prolapse, you've never used it in</p> <p>11 an ASC repair; is that accurate?</p> <p>12 A. Yeah, I would say that the hybrid mesh, the</p> <p>13 Ultrapro mesh, was my mesh of choice for a</p> <p>14 transvaginal application, but an abdominal</p> <p>15 sacrocolpopexy is a very different operation</p> <p>16 than a transvaginal mesh.</p> <p>17 Q. So even though an ASC is a very different</p> <p>18 operation than a transvaginal mesh, you have</p> <p>19 used the Gynemesh PS mesh in both of those</p> <p>20 applications, but you haven't used the</p> <p>21 Ultrapro mesh in both of those applications;</p> <p>22 is that accurate?</p> <p>23 A. That's accurate.</p> <p>24 Q. Do you believe that the Ultrapro mesh, which</p>

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<p>1 is also the Prolift+M mesh, is an appropriate</p> <p>2 choice for repair of ASC?</p> <p>3 A. That I don't know because I don't know that</p> <p>4 there is specific data to support the use of</p> <p>5 the so-called hybrid mesh for sacrocolpopexy.</p> <p>6 Q. If a physician were to use the Ultrapro mesh</p> <p>7 in an ASC repair, and again the Ultrapro mesh</p> <p>8 is the same as the Prolift+M mesh, do you</p> <p>9 believe that that would be within the standard</p> <p>10 of care for an ASC repair or not?</p> <p>11 MS. KATZ GERSTEL: Object to form.</p> <p>12 A. I mean, I've never used a hybrid mesh for an</p> <p>13 ASC; and, again, that's a vastly different</p> <p>14 operation than the transvaginal mesh kits.</p> <p>15 Standard of care, you know, there would have</p> <p>16 to be some data to support the use of Ultrapro</p> <p>17 in the abdominal space specifically for ASCs</p> <p>18 for me to say whether it could become standard</p> <p>19 of care.</p> <p>20 BY MR. FAES:</p> <p>21 Q. Have you ever looked or studied that question</p> <p>22 of whether there is data regarding the</p> <p>23 Ultrapro mesh for ASC?</p> <p>24 A. I am not aware of specific data for Ultrapro</p>	<p>1 different method of introduction and trocar</p> <p>2 retrieval or mesh arm retrieval and wanted me</p> <p>3 to trial it. So we trialed it on a couple of</p> <p>4 patients. It handled nicely, but I continued</p> <p>5 to use Prolift+M at that time.</p> <p>6 Q. Are you familiar with the Prosima device at</p> <p>7 all manufactured by Ethicon and Johnson &</p> <p>8 Johnson?</p> <p>9 A. I am.</p> <p>10 Q. Did anyone from Ethicon and Johnson & Johnson</p> <p>11 ever introduce that product to you or try to</p> <p>12 get you to use it?</p> <p>13 A. Yes.</p> <p>14 Q. And why did you choose not to try that device?</p> <p>15 A. I think that by the time that J & J introduced</p> <p>16 Prosima, I think that Prolift+M was already up</p> <p>17 and running. And I felt like the applications</p> <p>18 for Prosima were somewhat limited, and I think</p> <p>19 that Prosima was more geared towards surgeons</p> <p>20 who were not comfortable with trocar</p> <p>21 placement, and that was sort of the appeal of</p> <p>22 Prosima. It was a trocarless mesh device.</p> <p>23 Q. So you would agree that one of the potential</p> <p>24 appeals of the Prosima device was that it was</p>
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<p>1 for ASCs.</p> <p>2 Q. My question is have you actually looked for</p> <p>3 and studied that question?</p> <p>4 A. Well, I think I answered that. I'm not aware</p> <p>5 of any studies with ASC that use Ultrapro.</p> <p>6 So, yes, I've looked.</p> <p>7 Q. You've looked and you couldn't find any?</p> <p>8 A. Couldn't find any.</p> <p>9 Q. Other than the Prolift and Prolift+M kits,</p> <p>10 what other kits have you used for the</p> <p>11 treatment of pelvic organ prolapse?</p> <p>12 A. I mean, I've done cadaver labs or participated</p> <p>13 in cadaver labs for a Boston Sci product and</p> <p>14 AMS, but the only other mesh kit that I put</p> <p>15 into a human is the Coloplast Exair.</p> <p>16 Q. And how many Exairs did you put into live</p> <p>17 patients?</p> <p>18 A. I think I probably did two.</p> <p>19 Q. And why did you stop using the Coloplast Exair</p> <p>20 products after using it in only two patients?</p> <p>21 A. Well, it's not that I sort of was gearing up</p> <p>22 to use it or stop using it. The rep from</p> <p>23 Coloplast had a mesh kit which was</p> <p>24 polypropylene with a similar but slightly</p>	<p>1 trocarless, and it didn't require any trocar</p> <p>2 passes, correct?</p> <p>3 MS. KATZ GERSTEL: Object to form.</p> <p>4 A. I think that would appeal to some folks. I</p> <p>5 think I was certainly comfortable with trocar</p> <p>6 passage, and I didn't feel a need to adopt</p> <p>7 Prosima.</p> <p>8 BY MR. FAES:</p> <p>9 Q. Would you agree that one of the potential</p> <p>10 benefits of the Prosima device was that it did</p> <p>11 not require the use of mesh arms like the</p> <p>12 Prolift+M device?</p> <p>13 MS. KATZ GERSTEL: Object to form.</p> <p>14 A. I don't know that that was a benefit or a</p> <p>15 detriment to that product. To be honest with</p> <p>16 you, I really had very little interest in -- I</p> <p>17 didn't proctor or teach that product. I never</p> <p>18 put a single Prosima in a patient.</p> <p>19 But in terms of thinking about why mesh</p> <p>20 kits fail and all of that, on the one hand, I</p> <p>21 think that not having deep arms and having a</p> <p>22 trocarless application is maybe both a benefit</p> <p>23 as well as a detriment to the device. But,</p> <p>24 again, I don't know the literature well enough</p>

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<p>1 on Prosima to tell you.</p> <p>2 BY MR. FAES:</p> <p>3 Q. Would you agree or disagree that the use of</p> <p>4 mesh arms in a device like the Prolift+M can</p> <p>5 introduce unique risks to a patient as opposed</p> <p>6 to a mesh device for pelvic organ prolapse</p> <p>7 like the Prosima which does not include mesh</p> <p>8 arms?</p> <p>9 MS. KATZ GERSTEL: Object to form.</p> <p>10 A. Yeah, there would be risks unique to the</p> <p>11 passage of those trocars to then retrieve the</p> <p>12 mesh arms. So, yes, there are unique risks</p> <p>13 associated with retrieval of the mesh arms.</p> <p>14 BY MR. FAES:</p> <p>15 Q. Would you agree that when designing a mesh kit</p> <p>16 like the Prolift+M it would be beneficial to</p> <p>17 the patient and to patient safety to design</p> <p>18 the procedure to have as few trocar passes as</p> <p>19 possible?</p> <p>20 A. I don't know that I can say that trocar passes</p> <p>21 are what is responsible for, you know, issues</p> <p>22 with Prolift. Prolift is a pretty minimally</p> <p>23 invasive procedure; and I think that although,</p> <p>24 as we said yesterday I haven't designed a</p>	<p>1 as the Prolift+M, which requires multiple</p> <p>2 trocar passes, introduces additional risks to</p> <p>3 the patient because of those trocar passes as</p> <p>4 opposed to a device that requires less trocar</p> <p>5 passes like the AMS Elevate or a device that</p> <p>6 requires zero trocar passes like the Prosima?</p> <p>7 MS. KATZ GERSTEL: Object to form.</p> <p>8 A. Again, I don't think I can talk about the AMS</p> <p>9 product because I'm not familiar with their</p> <p>10 literature. I can't tell you how safe that</p> <p>11 product was. I don't know what adverse events</p> <p>12 were associated in the Prosima device. To me,</p> <p>13 it's sort of hypothetical that less trocar</p> <p>14 passage would equal more safety. I think I</p> <p>15 would need to look at a series, papers, and I</p> <p>16 haven't looked at the Prosima literature or</p> <p>17 the AMS literature.</p> <p>18 BY MR. FAES:</p> <p>19 Q. So you would agree then that you've never</p> <p>20 specifically studied the question or whether</p> <p>21 or not less trocar passes in a mesh kit such</p> <p>22 as the Prolift+M would equal more safety,</p> <p>23 correct?</p> <p>24 A. I mean, I don't think there's been a head-to-</p>
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<p>1 biomedical device or a mesh kit, I think I'm</p> <p>2 comfortable with the number of trocar passes,</p> <p>3 and I agree with the design of the device.</p> <p>4 Q. So you wouldn't agree that a device that has</p> <p>5 minimal or less or zero trocar passes is a</p> <p>6 potential safety benefit to a patient?</p> <p>7 A. I think ultimately the question would be, for</p> <p>8 me, I would have to look at that trocarless</p> <p>9 device and vet whatever mechanism is being</p> <p>10 used to potentially keep the mesh in place</p> <p>11 and/or look at its efficacy and failure rate.</p> <p>12 Q. Are you familiar with the AMS Elevate device?</p> <p>13 A. Vaguely.</p> <p>14 Q. Are you aware that the AMS Elevate device only</p> <p>15 requires one trocar passage as opposed to the</p> <p>16 Prolift+M device that requires up to six</p> <p>17 trocar passes?</p> <p>18 A. It's been a while since I've looked at, you</p> <p>19 know, alternate devices, so I can't tell you</p> <p>20 that -- I've never used an AMS mesh kit in a</p> <p>21 human.</p> <p>22 Q. So you would agree based on your previous</p> <p>23 responses that you've never specifically</p> <p>24 studied the question of whether a device such</p>	<p>1 head trial of a multi-trocar transvaginal mesh</p> <p>2 like Prolift versus a single trocar passage</p> <p>3 material like the AMS kit. I can tell you</p> <p>4 that the Prolift+M, despite having multiple</p> <p>5 trocar passages, I would feel to be safe.</p> <p>6 Q. Would you agree that I wouldn't expect you to</p> <p>7 be able to offer an opinion to a reasonable</p> <p>8 degree of medical certainty of whether or not</p> <p>9 if the Prolift+M kit had been designed with</p> <p>10 less trocar passes than it currently has</p> <p>11 whether or not that would be safer, more safe</p> <p>12 or less safe for a patient; is that accurate?</p> <p>13 MS. KATZ GERSTEL: Objection,</p> <p>14 hypothetical.</p> <p>15 A. I mean, it's a hypothetical question. You</p> <p>16 know, the French mesh group designed the</p> <p>17 device with, you know, two trocar passages on</p> <p>18 either side for the anterior and one on either</p> <p>19 side for the posterior. I don't know if less</p> <p>20 trocar passages would equal greater safety.</p> <p>21 And the other question would be for me is</p> <p>22 how you define safety. What adverse event are</p> <p>23 we looking to decrease with less trocar</p> <p>24 passage? That would be my question.</p>

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<p>1 MS. KATZ GERSTEL: Can we take a bathroom</p> <p>2 break?</p> <p>3 MR. FAES: Sure. I actually need one,</p> <p>4 too, but I wasn't going to be the one to cry</p> <p>5 uncle.</p> <p>6 (A break was taken.)</p> <p>7 BY MR. FAES:</p> <p>8 Q. Doctor, we're back on the record after a short</p> <p>9 break. Are you ready to proceed?</p> <p>10 A. Sure.</p> <p>11 Q. We may have talked about this some yesterday,</p> <p>12 but how many Prolift or Prolift+M meshes have</p> <p>13 you either excised or revised in the course of</p> <p>14 your career?</p> <p>15 A. Today you asked Prolift and Prolift+M.</p> <p>16 Yesterday I think we discussed only slings.</p> <p>17 Q. So my question is, just so it's clear for the</p> <p>18 record, how many Prolift or Prolift+M meshes</p> <p>19 have you excised or revised during the course</p> <p>20 of your career?</p> <p>21 A. I mean, I've probably done 60 mesh excisions</p> <p>22 or revisions; and of those, maybe two-thirds</p> <p>23 were Prolift. So maybe 40 out of the 60.</p> <p>24 Q. When you say 40, do you mean 40 Prolift or</p>	<p>1 rates or efficacy rates regarding the</p> <p>2 Prolift+M in your own patients?</p> <p>3 A. Yes.</p> <p>4 Q. And what is that opinion?</p> <p>5 A. I don't know that we specifically put my</p> <p>6 numbers in the Prolift+M section of my report;</p> <p>7 but I would say that my rate of exposure, I</p> <p>8 mean, it's kind of broad, and it's hard for me</p> <p>9 to sort of single out Prolift+M from the</p> <p>10 original Prolift. But I would say that my</p> <p>11 rate of exposure was probably anywhere from</p> <p>12 eight to 15 percent, at least.</p> <p>13 And when I've seen patients back for a</p> <p>14 Prolift+M, and I continue to see some of these</p> <p>15 patients, I have not seen anyone come back in</p> <p>16 symptomatic from a recurrent prolapse. But,</p> <p>17 then again, you know, maybe we haven't</p> <p>18 followed them out long enough, as time will</p> <p>19 tell.</p> <p>20 Q. So you believe that your rate of exposure with</p> <p>21 the Prolift+M specifically is somewhere</p> <p>22 between eight and 15 percent; is that</p> <p>23 accurate?</p> <p>24 A. Yes.</p>
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<p>1 Prolift+M, or do you mean 40 just Prolift?</p> <p>2 A. I don't have a specific breakdown of how many</p> <p>3 of the 40 were Prolift and how many were +M.</p> <p>4 Q. But in your mind, the 40 includes Prolift and</p> <p>5 Prolift+M, right?</p> <p>6 A. I would group them together, yes.</p> <p>7 Q. When you say 40 out of the 60, what is the 60</p> <p>8 referring to? Is that the number of excisions</p> <p>9 or revisions of pelvic organ prolapse mesh</p> <p>10 kits that you've revised in the course of your</p> <p>11 career, or is that something else?</p> <p>12 A. The 60 would include mesh from</p> <p>13 sacrocolpopexies and mesh from other</p> <p>14 manufacturer's kits.</p> <p>15 Q. So in about 240 cases you've put in a Prolift</p> <p>16 or Prolift+M, and in about 40 cases you've</p> <p>17 removed or excised a Prolift or Prolift+M</p> <p>18 mesh, correct?</p> <p>19 A. I mean, the majority of those patients who had</p> <p>20 a mesh revision or excision were not patients</p> <p>21 that I implanted. But your numbers are</p> <p>22 correct.</p> <p>23 Q. Do you intend to offer any opinions in this</p> <p>24 case regarding specifically any complication</p>	<p>1 Q. And how many patients is that based on?</p> <p>2 A. Again, it's hard for me to tease out the</p> <p>3 Prolift+M from the original Prolift kits. And</p> <p>4 I would also say that my exposure rate</p> <p>5 decreased in the time that I started with the</p> <p>6 original Prolift to when I ended with</p> <p>7 Prolift+M.</p> <p>8 So, you know, like I said, it's hard for</p> <p>9 me to sort of pull out just what my rate of</p> <p>10 exposure was for the Prolift+M patients. It</p> <p>11 all -- and I don't think that I saw much of a</p> <p>12 difference in rate of exposure between the</p> <p>13 original Prolift and the Prolift+M, but I</p> <p>14 think that over time my exposure rates</p> <p>15 decreased. I think that's more to changes in</p> <p>16 technique and other factors.</p> <p>17 Q. So the eight to 15 percent exposure rate, you</p> <p>18 can't be any more specific than that? You</p> <p>19 just have that range; is that accurate?</p> <p>20 A. Yeah, eight to 15 percent. I know it's kind</p> <p>21 of a broad range.</p> <p>22 Q. Would you agree that your opinions regarding</p> <p>23 your own personal experience with your</p> <p>24 patients regarding the Prolift+M is not based</p>

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<p>1 upon any formal analysis where you determined</p> <p>2 the exact number of patients, the number of</p> <p>3 patients that were lost to follow-up or any</p> <p>4 standardized evaluation protocol, correct?</p> <p>5 MS. KATZ GERSTEL: Object to form.</p> <p>6 A. Yeah, I haven't done a retrospective cohort</p> <p>7 analysis of my Prolift patients where I</p> <p>8 formally looked at it, but I feel like my mesh</p> <p>9 exposure rate is anywhere from eight to 15</p> <p>10 percent.</p> <p>11 BY MR. FAES:</p> <p>12 Q. In your expert report starting on page 17, you</p> <p>13 discuss mesh shrinkage, and you state that all</p> <p>14 experienced surgeons should know scar tissue</p> <p>15 can contract and, therefore, such contraction</p> <p>16 is expected. However, contraction of Gynemesh</p> <p>17 PS and macroporous polypropylene mesh itself</p> <p>18 has not been demonstrated. Do you see that?</p> <p>19 A. Yes.</p> <p>20 Q. Is that an opinion you intend to offer</p> <p>21 regarding the Prolift+M or Ultrapro mesh?</p> <p>22 A. Yes.</p> <p>23 Q. So you believe that contraction of the</p> <p>24 Ultrapro or Prolift+M mesh has not been</p>	<p>1 with the AMS kit that he didn't find mesh</p> <p>2 contracture or shrinkage. In fact, I think he</p> <p>3 found an increase in total vaginal length,</p> <p>4 which would be the opposite of what you would</p> <p>5 get with mesh shrinkage or contracture.</p> <p>6 BY MR. FAES:</p> <p>7 Q. So I'm not sure that I got an answer to my</p> <p>8 question that I understood. Are you saying</p> <p>9 that you agree with that statement, you</p> <p>10 disagree with it, or you can't answer it yes</p> <p>11 or no?</p> <p>12 A. Like I said, I think it's hard to say that</p> <p>13 there is mesh shrinkage when I don't know that</p> <p>14 we've defined or been able to sort of gauge or</p> <p>15 qualify what that means, you know. I've read</p> <p>16 -- I probably have the article here. I'm not</p> <p>17 as organized as you guys with your binders.</p> <p>18 So there is an article, and I can't</p> <p>19 remember if we discussed in the report</p> <p>20 although I sort of alluded to it, even Ben</p> <p>21 Feiner and Chris Maher's article, Vaginal Mesh</p> <p>22 Contraction, I don't think that they really</p> <p>23 were able to define or quantify mesh shrinkage</p> <p>24 or contracture in that article.</p>
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<p>1 demonstrated?</p> <p>2 A. As far as I know, in regards to my own</p> <p>3 patients and my review of the literature, I</p> <p>4 haven't seen a well-designed description of</p> <p>5 mesh shrinkage or contraction for the</p> <p>6 Prolift+M.</p> <p>7 Q. So do you agree or disagree that mesh</p> <p>8 contraction or shrinkage is a risk of</p> <p>9 transvaginal POP repair with mesh that has</p> <p>10 been reported in the published scientific</p> <p>11 literature?</p> <p>12 MS. KATZ GERSTEL: Object to form.</p> <p>13 A. I guess, you know, in my read of some of the</p> <p>14 literature describing mesh shrinkage slash</p> <p>15 contracture, I've had an issue sort of</p> <p>16 figuring out how they define or qualify or</p> <p>17 stage what they mean by mesh shrinkage and</p> <p>18 contracture. I think that part of, you know,</p> <p>19 physiological healing of a wound is that you</p> <p>20 have some mesh -- you have some wound</p> <p>21 contracture, but I haven't seen a convincing</p> <p>22 paper to say that there is such a thing. In</p> <p>23 fact, I think that we have a decent paper by</p> <p>24 Dietz at least in patients that he followed</p>	<p>1 So I don't know that I believe that mesh</p> <p>2 contracture or shrinkage happens.</p> <p>3 Q. Okay. So if the FDA concluded that mesh</p> <p>4 contracture does happen and has been reported</p> <p>5 in the scientific sign literature, you would</p> <p>6 disagree with the FDA?</p> <p>7 A. I think I would need to look at whatever</p> <p>8 papers the FDA has reviewed that have reported</p> <p>9 mesh contracture and sort of see how those</p> <p>10 authors defined mesh contracture or shrinkage.</p> <p>11 Clinically, I haven't found that in the case</p> <p>12 of TVTs, for instance, which is, you know,</p> <p>13 mesh, that there is any sort of mesh</p> <p>14 shrinkage. I think if there were mesh</p> <p>15 shrinkage or contracture that over time if</p> <p>16 this is a process that occurs over time that</p> <p>17 we would see patients coming in with urinary</p> <p>18 retention, more issues with urgency and LUTS</p> <p>19 symptoms. I haven't found that patients have</p> <p>20 had loss of vaginal length over time.</p> <p>21 In the patients with Prolift that I've</p> <p>22 seen, I haven't seen that they have developed</p> <p>23 more urgency or overactive bladder over time</p> <p>24 related to mesh shrinking or contracting, so I</p>

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<p>1 haven't seen it in my practice.</p> <p>2 Q. So just to be clear, you do not believe that</p> <p>3 mesh contracture occurs with the Prolift+M?</p> <p>4 A. Correct.</p> <p>5 Q. Can I have you look at the Prolift+M IFU that</p> <p>6 is marked as an exhibit in front of you, and</p> <p>7 specifically I want to have you look at the</p> <p>8 adverse reaction section on page number two.</p> <p>9 And if you look under adverse reactions, the</p> <p>10 first bullet point one of the adverse</p> <p>11 reactions listed is contracture. Do you see</p> <p>12 that?</p> <p>13 A. I'm sorry, under adverse reactions?</p> <p>14 Q. Yes, it's in the last line of the first bullet</p> <p>15 point, fistula formation, contracture,</p> <p>16 scarring, mesh exposure, erosion or extrusion?</p> <p>17 A. Mm-hmm.</p> <p>18 Q. So since you believe that mesh contracture</p> <p>19 does not occur, do you believe that Ethicon</p> <p>20 and Johnson & Johnson has provided inaccurate</p> <p>21 information in their Prolift+M IFU?</p> <p>22 MS. KATZ GERSTEL: Objection,</p> <p>23 mischaracterization.</p> <p>24 A. I guess, you know, the language that I would</p>	<p>1 A. I guess what I would have to know is whether,</p> <p>2 as you say, if there is a 30 to 50 percent</p> <p>3 contraction, does that -- how is that realized</p> <p>4 and does that mean -- how does that affect</p> <p>5 clinical outcomes. Just to say that there is,</p> <p>6 you know, 30 to 50 percent contraction of the</p> <p>7 mesh, I guess I would need to know is, number</p> <p>8 one, how did they document that. Number two,</p> <p>9 is it clinically relevant and what does that</p> <p>10 lead to.</p> <p>11 BY MR. FAES:</p> <p>12 Q. Let me ask you this, Doctor. Do you believe</p> <p>13 that a potential adverse reaction of the</p> <p>14 Prolift mesh is that excessive contraction or</p> <p>15 shrinkage of the tissue surrounding the mesh,</p> <p>16 vaginal scarring, tightening and/or shortening</p> <p>17 may occur?</p> <p>18 MS. KATZ GERSTEL: Andy, are you asking</p> <p>19 about Prolift or Prolift+M? You said Prolift.</p> <p>20 I just wanted to clarify.</p> <p>21 BY MR. FAES:</p> <p>22 Q. First, do you believe it's an adverse event of</p> <p>23 -- if you can answer is it an adverse event of</p> <p>24 both products, or do you believe it's only an</p>
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<p>1 sort of for me at least is that that sentence</p> <p>2 starts off with potential adverse reactions,</p> <p>3 so that's how I would sort of qualify</p> <p>4 contracture is that it's a potential adverse</p> <p>5 reaction. I don't know that I can say more</p> <p>6 about it than that. But, you know, J & J has</p> <p>7 it in their IFU that it's a potential</p> <p>8 reaction.</p> <p>9 BY MR. FAES:</p> <p>10 Q. Have you ever seen anything from any</p> <p>11 memorandums or findings from Ethicon's own</p> <p>12 medical director stating that they believe</p> <p>13 polypropylene mesh contracts 30 to 50 percent</p> <p>14 as a rule of thumb?</p> <p>15 MS. KATZ GERSTEL: Objection.</p> <p>16 A. I haven't seen those communications.</p> <p>17 BY MR. FAES:</p> <p>18 Q. If that is something Ethicon believed</p> <p>19 regarding their polypropylene meshes for the</p> <p>20 treatment of pelvic organ prolapse as early as</p> <p>21 2002, would that affect any of the opinions</p> <p>22 that you're offering in this case regarding</p> <p>23 the Prolift+M?</p> <p>24 MS. KATZ GERSTEL: Objection.</p>	<p>1 adverse event of one or the other?</p> <p>2 A. Which particular adverse reactions were you</p> <p>3 referring to? I'm sorry.</p> <p>4 Q. So I'll restate the question. Do you believe</p> <p>5 that a potential adverse reaction of the</p> <p>6 Prolift or Prolift+M mesh is that excessive</p> <p>7 contraction or shrinkage of the tissue</p> <p>8 surrounding the mesh, vaginal scarring,</p> <p>9 tightening and/or shortening may occur?</p> <p>10 A. I mean, I think those can occur in any</p> <p>11 reconstructive pelvic floor surgery regardless</p> <p>12 of whether mesh is used or not.</p> <p>13 Q. Do you think that is a reasonable warning to</p> <p>14 place in the adverse reaction section of the</p> <p>15 Prolift+M IFU?</p> <p>16 MS. KATZ GERSTEL: Object to form.</p> <p>17 A. I mean, I think it's a reasonable warning, but</p> <p>18 I think that those adverse events I think are</p> <p>19 well known to surgeons operating in this</p> <p>20 arena, in this space.</p> <p>21 BY MR. FAES:</p> <p>22 Q. At what time, at any time during when the</p> <p>23 Prolift+M was marketed and sold or now?</p> <p>24 A. Well, I think the majority of the adverse</p>

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<p>1 events that you listed can occur with any sort</p> <p>2 of prolapse repair. And so in that regard, I</p> <p>3 think they're well known to surgeons operating</p> <p>4 in that arena, and they were certainly known</p> <p>5 at the time that Prolift was available and had</p> <p>6 been known prior to, you know, the</p> <p>7 introduction of mesh kits.</p> <p>8 Q. Have you ever engaged in any kind of study or</p> <p>9 formal analysis of what percentage of surgeons</p> <p>10 actually know or knew about that particular</p> <p>11 adverse reaction during the time that the</p> <p>12 Prolift+M was marketed and sold?</p> <p>13 MS. KATZ GERSTEL: Object to form.</p> <p>14 A. When you say this particular adverse reaction,</p> <p>15 you are referring to --</p> <p>16 BY MR. FAES:</p> <p>17 Q. Excessive contraction or shrinkage of the</p> <p>18 tissue surrounding the mesh, vaginal scarring,</p> <p>19 tightening or shortening that may occur?</p> <p>20 A. I have not done a poll of other urology,</p> <p>21 urogyn, GYN surgeons about what they knew or</p> <p>22 read in the IFU.</p> <p>23 Q. So you can't state as you sit here today to a</p> <p>24 reasonable degree of medical certainty the</p>	<p>1 adverse reactions section of the Prolift or</p> <p>2 Prolift+M IFU that excessive contraction or</p> <p>3 shrinkage of the tissue surrounding the mesh,</p> <p>4 vaginal scarring, tightening and/or shortening</p> <p>5 may occur?</p> <p>6 A. I mean, as we talked about yesterday, I've</p> <p>7 never written an IFU, and I don't know the</p> <p>8 specifics of sort of what the FDA might</p> <p>9 require J&J to put in the IFU, although my</p> <p>10 recollection is that the FDA was involved with</p> <p>11 the construction of the IFU for Prolift+M.</p> <p>12 But, you know, sort of my impression of what</p> <p>13 needs to be in an IFU is I don't think that</p> <p>14 you need to put in what are commonly known</p> <p>15 risks and adverse reactions in the IFU. I</p> <p>16 think that it's nice that it's there. I don't</p> <p>17 know that it adds much to, you know, to either</p> <p>18 encouraging or deterring physicians from using</p> <p>19 the product. It certainly may help with</p> <p>20 informed consent for physicians who perhaps</p> <p>21 are unaware of this, but I offer the opinion</p> <p>22 that most pelvic surgeons would be aware of</p> <p>23 these adverse reactions. Common knowledge.</p> <p>24 Q. But my question is specifically since you</p>
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<p>1 percentage of pelvic floor surgeons who are</p> <p>2 aware or not aware of that particular risk; is</p> <p>3 that correct?</p> <p>4 MS. KATZ GERSTEL: Object to form.</p> <p>5 A. Again, my opinion is that these risks were</p> <p>6 commonly known for non-mesh procedures as well</p> <p>7 as mesh procedures. So, I mean, these are the</p> <p>8 risks of native tissue repairs apart from the</p> <p>9 use of the word mesh.</p> <p>10 Q. My question was a little different than that.</p> <p>11 My question was can you state to a reasonable</p> <p>12 degree of medical certainty the percentage of</p> <p>13 pelvic floor physicians in the United States</p> <p>14 who knew or didn't know about that particular</p> <p>15 risk during the time the Prolift+M mesh was</p> <p>16 sold?</p> <p>17 MS. KATZ GERSTEL: Object to form.</p> <p>18 A. I can't say what other people what their</p> <p>19 knowledge base was or what their experiences</p> <p>20 were. These risks, these adverse reactions</p> <p>21 were commonly known.</p> <p>22 BY MR. FAES:</p> <p>23 Q. Do you believe it's -- I take it that you</p> <p>24 believe it's unnecessary then to put in the</p>	<p>1 think that most physicians are aware and it's</p> <p>2 common knowledge, do you believe it's</p> <p>3 unnecessary to include that warning in the IFU</p> <p>4 for the Prolift or the Prolift+M mesh?</p> <p>5 MS. KATZ GERSTEL: Objection. Asked and</p> <p>6 answered?</p> <p>7 A. Again, I don't know that I have an opinion</p> <p>8 about it either way. I mean, we've already</p> <p>9 concluded and I've admitted that I've not</p> <p>10 written or contributed to IFUs.</p> <p>11 BY MR. FAES:</p> <p>12 Q. Okay. I think you've answered my question</p> <p>13 then, Doctor. Thank you.</p> <p>14 A. Okay.</p> <p>15 Q. Do you believe that neuromuscular problems</p> <p>16 including acute and/or chronic pain in the</p> <p>17 groin, thigh, leg, pelvic and/or abdominal</p> <p>18 area is a potential adverse reaction of the</p> <p>19 Prolift and Prolift+M mesh?</p> <p>20 A. I think that the majority of the adverse</p> <p>21 reactions that you listed are also potential</p> <p>22 adverse reactions of any prolapse procedure.</p> <p>23 Q. So, again, do you have any opinion of whether</p> <p>24 or not it is necessary or unnecessary to</p>

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<p>1 include that particular adverse reaction in</p> <p>2 the IFU for the Prolift+M?</p> <p>3 A. Again, I think I'm of the feeling that those</p> <p>4 were commonly known adverse reactions for any</p> <p>5 prolapse repair, so these would be common.</p> <p>6 This would be common knowledge amongst</p> <p>7 surgeons doing these procedures.</p> <p>8 Q. So with regard to that particular adverse</p> <p>9 reaction or set of adverse reactions, however</p> <p>10 you want to clarify it, would you agree that</p> <p>11 you haven't done any kind of formal analysis</p> <p>12 as to what percentage of pelvic floor</p> <p>13 physicians in the United States were aware</p> <p>14 that that was a potential adverse reaction of</p> <p>15 the Prolift+M during the time it was marketed?</p> <p>16 MS. KATZ GERSTEL: Object to form.</p> <p>17 A. I haven't done a formal analysis, no.</p> <p>18 BY MR. FAES:</p> <p>19 Q. And I need to re-ask the question because I'm</p> <p>20 not sure I got an answer.</p> <p>21 My question was specifically -- two</p> <p>22 questions ago my question was do you believe</p> <p>23 it is necessary or unnecessary to include a</p> <p>24 warning in the adverse reaction section of the</p>	<p>1 not necessary for them to be listed in the</p> <p>2 IFU.</p> <p>3 Q. So if Ethicon and Johnson & Johnson did</p> <p>4 actually put that risk in one of their IFUs</p> <p>5 for either the Prolift or Prolift+M mesh, you</p> <p>6 believe that Ethicon and Johnson & Johnson</p> <p>7 would be putting unnecessary information in</p> <p>8 their IFUs; is that correct?</p> <p>9 MS. KATZ GERSTEL: Object to form.</p> <p>10 A. I think that the information provided here is,</p> <p>11 as I said, commonly known to surgeons who are</p> <p>12 operating in this arena. When you say</p> <p>13 unnecessary to put it in, I don't see the harm</p> <p>14 in putting it in. I would probably say that</p> <p>15 the information if it were commonly known to</p> <p>16 surgeons operating in this arena was put in</p> <p>17 then it might be not so much unnecessary but</p> <p>18 perhaps it would be redundant.</p> <p>19 BY MR. FAES:</p> <p>20 Q. But you would agree that putting that</p> <p>21 particular risk in the Prolift+M IFU might</p> <p>22 actually be helpful to some physicians in</p> <p>23 discussing the risk of their device with the</p> <p>24 patient and doing informed consent?</p>
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<p>1 Prolift+M IFU that neuromuscular problems</p> <p>2 including acute and/or chronic pain in the</p> <p>3 groin, thigh, leg, pelvic and/or abdominal</p> <p>4 area may occur?</p> <p>5 A. I'm of the opinion that since these are</p> <p>6 adverse reactions that are commonly known to</p> <p>7 surgeons operating in this arena and can occur</p> <p>8 with non-mesh kits that it's not new</p> <p>9 territory. So, again, I've not written an</p> <p>10 IFU, but my understanding is that if adverse</p> <p>11 reactions or risks are common knowledge that</p> <p>12 the FDA doesn't require a manufacturer to add</p> <p>13 those things to the IFU. The fact that J&J</p> <p>14 puts those things into the IFU I think is</p> <p>15 helpful, and I think -- but I don't know that</p> <p>16 it adds a whole lot to the IFU.</p> <p>17 Q. But my question was specifically can you</p> <p>18 answer yes or no do you believe it's necessary</p> <p>19 or unnecessary to -- strike that.</p> <p>20 Can you answer yes or no do you believe</p> <p>21 it's necessary to include those risks in the</p> <p>22 IFU for the Prolift+M or not?</p> <p>23 A. I think if they're commonly known risks</p> <p>24 associated with any prolapse repair that it's</p>	<p>1 MS. KATZ GERSTEL: Objection.</p> <p>2 A. Absolutely.</p> <p>3 BY MR. FAES:</p> <p>4 Q. And same question with regard to the risk of</p> <p>5 excessive contraction or shrinkage of the</p> <p>6 tissue surrounding the mesh. Would you agree</p> <p>7 with that as well?</p> <p>8 MS. KATZ GERSTEL: Objection.</p> <p>9 A. In regards to helping counseling patients,</p> <p>10 absolutely.</p> <p>11 BY MR. FAES:</p> <p>12 Q. Would it be helpful in reminding doctors that</p> <p>13 that is a potential risk of the Prolift+M</p> <p>14 procedure?</p> <p>15 MS. KATZ GERSTEL: Objection.</p> <p>16 A. I mean, when I was a proctor, I would try to</p> <p>17 review a lot of this at the cadaver stations</p> <p>18 and also review these sorts of things when</p> <p>19 people would come to my hospital and watch</p> <p>20 surgery. I think more education is better</p> <p>21 than less education.</p> <p>22 BY MR. FAES:</p> <p>23 Q. So you would agree then that it might be</p> <p>24 helpful in reminding the doctor that that</p>

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<p>1 excessive contraction is a potential risk of</p> <p>2 the Prolift+M IFU by including it in the</p> <p>3 adverse reactions section of the IFU, correct?</p> <p>4 MS. KATZ GERSTEL: Objection.</p> <p>5 A. It can't hurt, so yes.</p> <p>6 BY MR. FAES:</p> <p>7 Q. Would you agree with me that serious</p> <p>8 complications associated with surgical mesh</p> <p>9 for transvaginal repair of pelvic organ</p> <p>10 prolapse are not rare?</p> <p>11 MS. KATZ GERSTEL: Objection.</p> <p>12 A. I guess I would need to know how you define a</p> <p>13 serious adverse event.</p> <p>14 BY MR. FAES:</p> <p>15 Q. Well, you know the FDA has actually issued a</p> <p>16 statement stating that serious complications</p> <p>17 associated with surgical mesh for transvaginal</p> <p>18 repair of pelvic organ prolapse are not rare,</p> <p>19 correct?</p> <p>20 A. I did read that statement, and one questions</p> <p>21 how they define serious adverse events.</p> <p>22 Q. So can you answer yes or no whether or not you</p> <p>23 agree or disagree with the FDA statement</p> <p>24 regarding whether or not serious complications</p>	<p>1 pelvic organ prolapse are rare -- are not</p> <p>2 rare? Sorry.</p> <p>3 A. I would. You can have serious adverse events</p> <p>4 with any procedure for prolapse and/or</p> <p>5 incontinence. And, again, the issue I have</p> <p>6 with the FDA warning from 2008 and then the</p> <p>7 subsequent follow-up in 2011 is that there is</p> <p>8 no denominator. And it's also very unclear as</p> <p>9 to what they define as serious adverse events.</p> <p>10 My understanding is that the majority of</p> <p>11 the so-called serious adverse events were</p> <p>12 related to mesh exposure. And I wouldn't</p> <p>13 consider exposure of mesh to be a serious</p> <p>14 adverse event. It's not life threatening. It</p> <p>15 typically doesn't require rehospitalization.</p> <p>16 Typically doesn't require re-operation.</p> <p>17 Exposure of the mesh is oftentimes</p> <p>18 asymptomatic. Mesh exposure typically doesn't</p> <p>19 lead to persistent or significant disability,</p> <p>20 and the interventions to correct a mesh</p> <p>21 exposure aren't meant to correct disability,</p> <p>22 aren't going to save or decrease the rate of</p> <p>23 rehospitalization and/or prevent a life-</p> <p>24 threatening condition.</p>
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<p>1 with transvaginal mesh for POP are rare?</p> <p>2 A. Again, I guess my issue is how the FDA defined</p> <p>3 serious adverse events. There was a nice</p> <p>4 poster presentation from a recent AUGS</p> <p>5 meeting. And, again, what they did was they</p> <p>6 did a systematic review of the literature.</p> <p>7 Again, that's different than the MAUDE</p> <p>8 database, but they did a systematic review of</p> <p>9 the literature between 2005 and 2016, and they</p> <p>10 looked at the rate of serious adverse events</p> <p>11 in the literature. And how they defined</p> <p>12 serious adverse events was hemorrhage,</p> <p>13 contraction, mesh infection requiring surgery,</p> <p>14 injury to visceral structures and fistula.</p> <p>15 And then they also looked at the rate of</p> <p>16 serious adverse events of mesh versus</p> <p>17 traditional repair in ASC.</p> <p>18 So based on the review of the literature</p> <p>19 as opposed to the problematic reporting up to</p> <p>20 the MAUDE database, I would say that serious</p> <p>21 adverse events are rare.</p> <p>22 Q. So you then would disagree with the statement</p> <p>23 that serious complications associated with</p> <p>24 surgical mesh for transvaginal repair of</p>	<p>1 Q. Would you agree or disagree that mesh erosion</p> <p>2 can require multiple surgeries to repair and</p> <p>3 can be debilitating in someone?</p> <p>4 MS. KATZ GERSTEL: Object to form.</p> <p>5 A. When you say debilitating, are you referring</p> <p>6 to the surgery to remove the mesh, or are you</p> <p>7 referring to the mesh exposure itself as</p> <p>8 debilitating?</p> <p>9 BY MR. FAES:</p> <p>10 Q. I'm referring to the consequences on the</p> <p>11 patient's quality of life and ability to</p> <p>12 engage in everyday activities.</p> <p>13 A. You know, when I counsel patients about these</p> <p>14 operations, all prolapse repairs, we talk</p> <p>15 about quality of life. And these women have</p> <p>16 pretty significant impaired quality of life</p> <p>17 from prolapse and from urinary incontinence,</p> <p>18 and we talk about the potential improvement</p> <p>19 for quality of life with these operations; but</p> <p>20 we also talk about how complications from</p> <p>21 these surgeries that are meant to improve</p> <p>22 quality of life can lead to worsening of</p> <p>23 quality of life.</p> <p>24 In my experience, yes, sometimes removing</p>

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<p>1 mesh can require multiple surgeries. I have 2 not seen patients where I've removed mesh left 3 with significant disability after removing 4 mesh, and I have not seen people have 5 inability to perform their activities of daily 6 living because of a mesh complication. 7 Q. So getting back to my question again, you 8 would agree that mesh erosion from pelvic 9 organ prolapse can require multiple surgeries 10 to repair and can be debilitating in some 11 women. Would you agree or disagree with that? 12 A. That's possible. 13 Q. So in cases where the pelvic organ prolapse 14 mesh does require multiple surgeries and ends 15 up being debilitating to women, do you 16 consider that to be a serious adverse event or 17 not, or does it have to be life threatening to 18 you in order to be a serious adverse event? 19 MS. KATZ GERSTEL: Objection. 20 A. Well, at least for Dr. Lowman who did this 21 poster at AUGS, she didn't consider however 22 you define life disabling as a serious adverse 23 event. So I guess, you know, I would have to 24 sort of take it on a case-by-case basis to</p>	<p>1 multiple mesh revisions cause debilitating 2 injury to a woman and affect her way of life 3 that you still don't consider that a serious 4 adverse event? Yes or no. 5 MS. KATZ GERSTEL: Object to form. 6 A. I guess that would be an adverse event related 7 to the mesh revision surgery as opposed to the 8 mesh being placed. It's hard to answer that 9 question. 10 BY MR. FAES: 11 Q. What if the mesh erosion from the POP kit 12 requires multiple surgeries to repair, is 13 debilitating to the woman, and that becomes -- 14 and because of the debilitating injury the 15 woman becomes suicidal and it's then life 16 threatening. Does that then qualify in your 17 mind as a serious adverse event? 18 MS. KATZ GERSTEL: Object to form. 19 A. I guess I would really need to learn more 20 about how you define debilitating and, you 21 know, what that means. In my experience, I 22 have not seen patients disabled from either a 23 mesh kit or from surgery to revise a mesh kit 24 or from, you know, the exposures that for the</p>
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<p>1 sort of, you know, learn more about what that 2 individual patient was experiencing. 3 My own experience has been that people do 4 quite well with these procedures, and they 5 don't suffer disability or disabling 6 complications like what you're asking about. 7 BY MR. FAES: 8 Q. But getting back to my question, do you 9 believe that a mesh erosion that requires 10 multiple surgeries to repair and is 11 debilitating to a woman, can that potentially 12 be a serious adverse event according to your 13 definition, or do you require the event to be 14 life threatening in order for it to be 15 considered a serious adverse event? 16 MS. KATZ GERSTEL: Object to form. 17 A. I mean, the reason why we do these operations 18 is to help people, not hurt them. If someone 19 ends up with, you know, a complication, I take 20 it pretty seriously. But most of us, I think, 21 would define a serious adverse event as a 22 life-threatening condition. 23 BY MR. FAES: 24 Q. So are you saying that in a case where</p>	<p>1 most part can be treated nonsurgically and can 2 be treated medically. 3 BY MR. FAES: 4 Q. So it's your testimony that you've never seen 5 a woman that has been debilitated from 6 complications from a pelvic organ prolapse 7 mesh? 8 MS. KATZ GERSTEL: Object to form. 9 A. I guess I'm still wondering how we're defining 10 debilitating, number one. And I've removed 11 mesh from women who have had pain with 12 intercourse, exposures. I removed sling mesh 13 from the urethra in women who have had 14 urethral injuries. I don't know how we're 15 defining debilitating. 16 BY MR. FAES: 17 Q. Doctor, I'm going to hand you what's been 18 marked as Exhibit No. 5 to your deposition. 19 And this is an e-mail dated May 28, 2014, and 20 if I can have you turn actually to the last 21 page which is the beginning of the e-mail 22 string. And you see at the top it states that 23 the product is Gynemesh, and that's the mesh 24 that is used in the Prolift device, correct?</p>

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<p>1 A. Correct.</p> <p>2 Q. And you look under details and it states, It</p> <p>3 was reported that the patient underwent a</p> <p>4 surgical procedure on 4/27/05 and TVT and</p> <p>5 Gynemesh were implanted. It was reported that</p> <p>6 she experienced pain, erosion of her internal</p> <p>7 bodily tissue and other injuries following the</p> <p>8 procedure. It was reported that the patient</p> <p>9 has undergone multiple surgeries and</p> <p>10 revisionary procedures. No additional</p> <p>11 information was provided. Do you see that?</p> <p>12 A. I do.</p> <p>13 MS. KATZ GERSTEL: Object. This e-mail</p> <p>14 does not appear to pertain to a Prolift+M.</p> <p>15 MR. FAES: Your objection is noted.</p> <p>16 BY MR. FAES:</p> <p>17 Q. And, again, just to clarify before I go to my</p> <p>18 next question, your testimony was that you</p> <p>19 haven't seen a woman debilitated from mesh</p> <p>20 from pelvic organ prolapse in your experience,</p> <p>21 correct?</p> <p>22 A. Again, I'm not too sure what we mean by</p> <p>23 debilitated, but I really don't have a clear</p> <p>24 recollection of anyone being significantly</p>	<p>1 particular patient.</p> <p>2 Q. So do you believe that this report is</p> <p>3 inaccurate?</p> <p>4 MS. KATZ GERSTEL: Objection.</p> <p>5 A. Well, I believe -- there's my name, and,</p> <p>6 again, I don't have this person's medical</p> <p>7 record in front of me to substantiate the</p> <p>8 procedures that I did on her, and I also don't</p> <p>9 have the medical record to substantiate what</p> <p>10 her complaints were. So I don't know what I</p> <p>11 can say about those.</p> <p>12 BY MR. FAES:</p> <p>13 Q. Do you believe that a patient who has</p> <p>14 undergone multiple revisionary procedures</p> <p>15 including four different mesh excisions across</p> <p>16 a period of at least three years and is</p> <p>17 experiencing pain, erosion, bleeding,</p> <p>18 dyspareunia and vaginal scarring is</p> <p>19 debilitated or not, or can you not answer from</p> <p>20 this information?</p> <p>21 MS. KATZ GERSTEL: Object to form.</p> <p>22 A. I mean, I think I'd have to know how she was</p> <p>23 before the surgery as well.</p> <p>24 You know, there are a lot of people that</p>
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<p>1 debilitated by mesh.</p> <p>2 Q. Okay. If you turn to the first page, at the</p> <p>3 top it states, It was reported that during</p> <p>4 insertion the patient experienced pain,</p> <p>5 erosion, extrusion, infection, urinary/bowel</p> <p>6 problems, recurrence, bleeding, dyspareunia,</p> <p>7 and vaginal scarring. Then it goes on to</p> <p>8 state, It was reported that patient underwent</p> <p>9 mesh excision on 11/11/2005, 1/06/2006,</p> <p>10 12/17/2007, 12/01/2008 by Ted M. Roth due to</p> <p>11 exposure and dyspareunia. Do you see that?</p> <p>12 A. I do.</p> <p>13 Q. Do you have a recollection upon reviewing this</p> <p>14 document of any patient that you've treated</p> <p>15 with pelvic organ prolapse mesh that fits this</p> <p>16 particular profile?</p> <p>17 A. I mean, I have a pretty good memory for a lot</p> <p>18 of things, but I honestly don't remember doing</p> <p>19 multiple procedures on one particular person.</p> <p>20 Q. So do you have any recollection of any patient</p> <p>21 that you've treated that had four different</p> <p>22 revision surgeries of a pelvic organ prolapse</p> <p>23 mesh product?</p> <p>24 A. I don't recall. I don't remember this</p>	<p>1 have pain, urinary and bowel problems,</p> <p>2 bleeding, dyspareunia, scarring before they</p> <p>3 have surgery. You know, it's hard for me to,</p> <p>4 you know, answer your question without having</p> <p>5 all of the information in front of me. We</p> <p>6 have three sentences.</p> <p>7 BY MR. FAES:</p> <p>8 Q. So you would agree with me then that a report</p> <p>9 of a woman who has underwent four different</p> <p>10 mesh excisions over a period of three years,</p> <p>11 has pain, erosion, extrusion, infection,</p> <p>12 urinary/bowel problems, recurrence, bleeding,</p> <p>13 dyspareunia and vaginal scarring, assuming</p> <p>14 those are all related to the prolapse mesh,</p> <p>15 you're still not able to determine whether or</p> <p>16 not that patient can be considered to have had</p> <p>17 a debilitating mesh injury?</p> <p>18 MS. KATZ GERSTEL: Objection.</p> <p>19 A. Not to be difficult, but I would still need to</p> <p>20 know sort of what her baseline was like prior</p> <p>21 to, you know, having whatever procedure she</p> <p>22 had. I would need to know whether she was</p> <p>23 having pain before the procedure, whether she</p> <p>24 was having infections or bowel problems, what</p>

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<p>1 degree prolapse she has because, again, 2 recurrence, assuming that is recurrence of 3 prolapse, you know, there is no single 4 operation that is 100 percent guaranteed to 5 not lead to recurrent prolapse. I would also 6 need to know whether she was having 7 dyspareunia before her procedure or, you know, 8 what vaginal scarring means. 9 I don't know that I can answer your 10 question without looking at this woman's 11 medical record. 12 BY MR. FAES: 13 Q. So you would agree then that the fact that a 14 woman has had four different excisions of a 15 pelvic organ prolapse mesh over a period of 16 three years, it's not reasonable to conclude 17 that that particular patient has likely 18 experienced some pain as a result of those 19 multiple procedures and multiple revisions? 20 MS. KATZ GERSTEL: Objection, 21 hypothetical. 22 A. It's hard to know what she has resulted in as 23 a result of those four procedures. My 24 experience with removing mesh and sort of what</p>	<p>1 have a mesh excision because her partner felt 2 the mesh when they had coitus? I don't know. 3 I would be happy to review the medical record. 4 BY MR. FAES: 5 Q. So all of those potential causes for those 6 excisions of the mesh, you wouldn't consider 7 any of those to be serious adverse events 8 because none of them are life threatening, 9 correct? 10 MS. KATZ GERSTEL: Objection. 11 A. The exposure of mesh and the fact that there 12 is a failure rate of mesh and the potential 13 for revision or reoperation, these are the 14 risks of not only mesh surgery but native 15 tissue repairs as well as sacrocolpopexy, 16 which is mesh but not in this space. 17 BY MR. FAES: 18 Q. If a patient is unable to -- excuse me, I'm 19 going to start over. 20 If a patient is unable to comfortably 21 engage in sexual intercourse for the rest of 22 their life as the result of a Prolift+M or 23 other prolapse mesh, would you consider that 24 to be a serious adverse event?</p>
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<p>1 has been put out in the literature is that 2 typically you can resolve a lot of the 3 purported problems of pain with removing the 4 mesh, and albeit it may require more than one 5 operation. But, you know, more times than 6 not, people are left with a reduction in their 7 pain. 8 BY MR. FAES: 9 Q. Could you conclude from this report of a 10 person -- strike that. 11 Could you conclude that if a person has 12 had four separate mesh excisions of a pelvic 13 organ prolapse mesh over a period of four 14 years that that patient more likely than not 15 experienced pain from those multiple 16 extrusions or exposures prior to the mesh 17 revision surgeries? 18 MS. KATZ GERSTEL: Objection. 19 A. I mean, there is no way to know, at least 20 looking at this, why she had the mesh 21 excisions four times. Did she have a mesh 22 excision because she was in pain? Did she 23 have a mesh excision because she was bothered 24 by vaginal discharge and bleeding? Did she</p>	<p>1 MS. KATZ GERSTEL: Objection. 2 A. You know, I mean -- 3 Q. Respectfully, I think, Doctor, this is a yes 4 or no question. So I would ask, if you can, 5 to first answer the question yes, no, or I 6 don't know. Then if you need to add an 7 explanation to the end of that, feel free to 8 do so, but I would like an answer to my 9 question first, please. 10 MS. KATZ GERSTEL: I object to that and 11 say, Doctor, you should answer the question as 12 you need to in order to be truthful and 13 accurate. 14 MR. FAES: Respectfully, Counsel, you 15 know that's not the rule. If we need to call 16 Judge Eifert and discuss it, we can. But you 17 know from Judge Eifert the rule is if you're 18 asked a yes or no question, you need to answer 19 the question yes or no or I don't know. And 20 if you need to -- or you can't answer the 21 question yes or no, then if you need to offer 22 an explanation to the end of that to make your 23 answer complete, you can feel free to do so. 24 But Judge Eifert has ruled on this</p>

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<p>1 multiple, multiple times on what the rule in 2 these depositions is. So if that is your 3 position, I think we should stop the 4 deposition right now and call Judge Eifert so 5 we can get a responsive answer to the 6 question. 7 MS. KATZ GERSTEL: I'm going to allow the 8 doctor to answer the question as he needs to 9 to be truthful and accurate. If he can answer 10 with a yes or no, fine. 11 A. Would you be so kind as to repeat the question 12 at this point? 13 MR. FAES: Can I have the court reporter 14 please read back the question. 15 (The pending question was read back 16 by the reporter.) 17 A. I can't answer that with a yes or no. 18 BY MR. FAES: 19 Q. Fair enough, Doctor. Doctor, if a person 20 experiences chronic debilitating pain for the 21 rest of their life as the result of a 22 Prolift+M or other prolapse mesh, would you 23 consider that to be a serious adverse event or 24 not? Yes or no.</p>	<p>1 A. I think what I said to Mr. Faes was that I 2 can't validate much of anything without 3 looking at this woman's medical record. 4 Q. Doctor, can pelvic organ prolapse impact a 5 woman's quality of life? 6 A. Yes. 7 Q. How? 8 A. It may cause significant discomfort, pain, 9 back pain, have a decrease in their ability to 10 perform their activities of daily living, 11 dyspareunia, loss of intimacy, feelings of 12 shame and even guilt over that. It can have 13 pretty significant impact on their quality of 14 life. 15 Q. And do you see patients in your own practice 16 that experience those negative impacts on 17 their quality of life because they suffer 18 pelvic organ prolapse? 19 A. Yes. 20 Q. Do you have patients in whom you have 21 implanted Prolift+M that you have followed for 22 years after their surgery? 23 A. Yes. 24 Q. Do you actually tend to see your patients in</p>
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<p>1 MS. KATZ GERSTEL: Same objection. 2 A. I can't answer that with a yes or no. 3 MR. FAES: Doctor, I think I'm about out 4 of time. So if I have any time left, I will 5 reserve the balance of that for redirect. 6 Thank you very much. 7 CROSS-EXAMINATION 8 BY MS. KATZ GERSTEL: 9 Q. Doctor, you were asked a moment ago about 10 Exhibit No. 5 which is an e-mail string; is 11 that correct? 12 A. Yeah. 13 Q. And do you see the e-mail string where it 14 starts on the page ending in 0129? 15 A. Yes. 16 Q. It's dated Wednesday, October 30, 2013? 17 A. Correct. 18 Q. And some of the information in that e-mail is 19 redacted, but do you see in this e-mail where 20 it says initial reporter: attorney? 21 A. Yes. 22 Q. Is there any way to verify or validate these 23 claimed injuries which were reported by an 24 attorney just by reading this e-mail?</p>	<p>1 whom you implanted a Prolift+M -- strike that. 2 Do the patients in whom you have implanted a 3 Prolift+M for the most part return to you for 4 follow-up care? 5 MR. FAES: Object to form. 6 A. Yeah. I mean, that's my impression; but the 7 other side of the coin is if they didn't 8 return to me, I have a pretty good 9 relationship with the other surgeons in the 10 state who might care for those patients, and 11 we keep an open line of communication about 12 patients who don't necessarily return to the 13 implant or the original consulting physician. 14 BY MS. KATZ GERSTEL: 15 Q. And for those reasons, do you, therefore -- 16 strike that. 17 Doctor, for those reasons, are you 18 therefore able to make an assessment of how 19 your patients in whom you have implanted 20 Prolift+M do for years following their 21 surgeries? 22 A. Yes. 23 MR. FAES: Object to form. 24 BY MS. KATZ GERSTEL:</p>

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<p>1 Q. Are the results that you've had with your</p> <p>2 patients in whom you've implanted Prolift+M</p> <p>3 consistent with the medical literature?</p> <p>4 A. Yes, that's my feeling.</p> <p>5 Q. For most of your patients in whom you've</p> <p>6 implanted Prolift+M, has Prolift+M improved</p> <p>7 their quality of life?</p> <p>8 MR. FAES: Object to form.</p> <p>9 A. Yes.</p> <p>10 BY MS. KATZ GERSTEL:</p> <p>11 Q. For most of your patients in whom you've</p> <p>12 implanted Prolift+M, even years after their</p> <p>13 surgery, are most of them still doing well?</p> <p>14 MR. FAES: Object to form.</p> <p>15 A. Yes.</p> <p>16 Q. Does Prolift+M have advantages that non-mesh</p> <p>17 pelvic floor repair surgeries don't have?</p> <p>18 A. I mean, I feel that there's enough data in the</p> <p>19 literature to support the use of mesh in the</p> <p>20 anterior compartment. And I think that the</p> <p>21 way I sort of think about patient selection is</p> <p>22 it's not that there is, you know, what are the</p> <p>23 indications for mesh, but who is the best</p> <p>24 patient for mesh or who would mesh be best in;</p>	<p>1 presentations at the medical society? Yes,</p> <p>2 I do.</p> <p>3 Q. Do you base your opinions on Prolift+M on the</p> <p>4 scientific data in the peer-reviewed medical</p> <p>5 literature and your conversations with your</p> <p>6 surgical colleagues and the medical society</p> <p>7 conferences that you attend?</p> <p>8 A. I do.</p> <p>9 MR. FAES: Object to form.</p> <p>10 BY MR. KATZ GERSTEL:</p> <p>11 Q. And also on your own practice?</p> <p>12 A. I do, yes.</p> <p>13 Q. Can serious adverse events result from any</p> <p>14 pelvic floor repair surgery?</p> <p>15 MR. FAES: Object to form.</p> <p>16 A. As I've defined serious adverse events, yes.</p> <p>17 And as what other adverse events were also</p> <p>18 discussed, as we discussed, can occur with all</p> <p>19 prolapse repairs.</p> <p>20 Q. Including non-mesh repairs?</p> <p>21 A. Correct.</p> <p>22 Q. Are the majority of the complications you have</p> <p>23 seen in Prolift+M patients treatable?</p> <p>24 A. Yes.</p>
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<p>1 and I think that there is certainly a role for</p> <p>2 mesh in patients with recurrent prolapse or</p> <p>3 advanced stages of prolapse, patients at risk</p> <p>4 for recurrent prolapse, i.e., folks with</p> <p>5 levator avulsion.</p> <p>6 So, yeah, absolutely there is a role for</p> <p>7 Prolift+M specifically in the anterior</p> <p>8 compartment, and there may be a role for mesh</p> <p>9 in the posterior compartment in patients who</p> <p>10 have perhaps failed repairs at least based on</p> <p>11 one study that I reviewed.</p> <p>12 Q. Doctor, do you regularly read the peer-</p> <p>13 reviewed medical literature on transvaginal</p> <p>14 mesh prolapse repairs?</p> <p>15 A. I do.</p> <p>16 Q. Do you confer with your colleagues, your</p> <p>17 surgical colleagues about transvaginal mesh</p> <p>18 prolapse repairs?</p> <p>19 A. I do.</p> <p>20 Q. Do you attend medical society conferences --</p> <p>21 strike that.</p> <p>22 Do you attend medical society conference</p> <p>23 events on transvaginal mesh prolapse repairs?</p> <p>24 A. When you say events, you mean posters and</p>	<p>1 Q. Are the complications that you've seen in your</p> <p>2 own practice -- strike that.</p> <p>3 Are the kinds of complications after</p> <p>4 Prolift+M that you've seen in your own</p> <p>5 practice the same complications that you have</p> <p>6 seen reported in the literature over time?</p> <p>7 MR. FAES: Object to form.</p> <p>8 A. Yes.</p> <p>9 BY MS. KATZ GERSTEL:</p> <p>10 Q. Are the complications that can occur with</p> <p>11 Prolift+M all complications that can occur</p> <p>12 with abdominal sacrocolpopexy?</p> <p>13 MR. FAES: Object to form.</p> <p>14 A. Yes.</p> <p>15 BY MS. KATZ GERSTEL:</p> <p>16 Q. Are the complications that can occur with</p> <p>17 Prolift+M all complications that can occur</p> <p>18 with non-mesh pelvic floor repairs?</p> <p>19 A. Yes.</p> <p>20 Q. Is exposure or erosion a complication that can</p> <p>21 happen even with sutures used in non-mesh</p> <p>22 pelvic floor repairs?</p> <p>23 A. Yes.</p> <p>24 MR. FAES: Object to form.</p>

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<p>1 Q. Having implanted some 80 Prolift+M and then</p> <p>2 followed your patients for years afterwards,</p> <p>3 are you an expert in how a woman's body reacts</p> <p>4 to the implantation of mesh with a Prolift+M?</p> <p>5 MR. FAES: Object to form.</p> <p>6 A. Inasmuch as I've been able to follow my</p> <p>7 patients over years, yes.</p> <p>8 BY MS. KATZ GERSTEL:</p> <p>9 Q. Having implanted some 80 Prolift+Ms and then</p> <p>10 followed your patients for years afterward,</p> <p>11 are you an expert in how the design of</p> <p>12 Prolift+M minimizes trauma to a woman's body</p> <p>13 compared to other non-mesh prolapse repairs?</p> <p>14 MR. FAES: Object to form.</p> <p>15 A. Yes.</p> <p>16 BY MS. KATZ GERSTEL:</p> <p>17 Q. How does the design of the Prolift+M minimize</p> <p>18 trauma to a woman's body?</p> <p>19 A. I mean, it's a minimally invasive means of</p> <p>20 providing support to one or multiple</p> <p>21 compartments of the vagina. Abdominal</p> <p>22 sacrocolpopexy, I would argue, is at times a</p> <p>23 maximally invasive means of doing something</p> <p>24 similar but can't address all of the</p>	<p>1 MR. FAES: Object to form.</p> <p>2 A. That's my opinion, yes.</p> <p>3 BY MS. KATZ GERSTEL:</p> <p>4 Q. How is it that experienced pelvic floor</p> <p>5 surgeons are knowledgeable of the risks of</p> <p>6 Prolift+M before they read an IFU?</p> <p>7 MR. FAES: Object to form.</p> <p>8 A. I think it's a combination of training, and</p> <p>9 hopefully they also read the peer-reviewed</p> <p>10 medical literature and that they're</p> <p>11 experienced with other forms of prolapse</p> <p>12 repair that have the same warnings and risk of</p> <p>13 adverse events.</p> <p>14 BY MS. KATZ GERSTEL:</p> <p>15 Q. In your opinion, does the Prolift+M IFU</p> <p>16 appropriately warn pelvic floor surgeons of</p> <p>17 the risk of Prolift+M?</p> <p>18 MR. FAES: Object to form.</p> <p>19 A. I feel that it does.</p> <p>20 MS. KATZ GERSTEL: I think that's all I</p> <p>21 have.</p> <p>22 REDIRECT EXAMINATION</p> <p>23 BY MR. FAES:</p> <p>24 Q. I just have a couple follow-up questions for</p>
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<p>1 compartment.</p> <p>2 So I think in that regard, I think that</p> <p>3 the Prolift or rather the construction of the</p> <p>4 Prolift and the application of the Prolift is</p> <p>5 minimally invasive and provides minimal tissue</p> <p>6 trauma.</p> <p>7 Q. Do the trocars allow for the Prolift+M to be a</p> <p>8 minimally invasive surgery?</p> <p>9 A. Yes.</p> <p>10 Q. As an implanter of Prolift+M as well as a</p> <p>11 surgeon who performs other non-mesh pelvic</p> <p>12 floor repairs, regularly reads the</p> <p>13 peer-reviewed medical literature on pelvic</p> <p>14 floor repairs, attends medical society</p> <p>15 conferences and confers with colleagues on</p> <p>16 pelvic floor repairs, Dr. Roth, are you an</p> <p>17 expert in the warnings surgeons need to have</p> <p>18 prior to performing the Prolift+M?</p> <p>19 MR. FAES: Object to form.</p> <p>20 A. Yes.</p> <p>21 BY MS. KATZ GERSTEL:</p> <p>22 Q. Are experienced pelvic floor surgeons commonly</p> <p>23 aware of all of the risks of Prolift+M before</p> <p>24 reading the IFU?</p>	<p>1 you, Doctor.</p> <p>2 Earlier, I think defense counsel was</p> <p>3 asking you whether or not the complications</p> <p>4 for a non-mesh prolapse surgery are all the</p> <p>5 same for a mesh repair of pelvic organ</p> <p>6 prolapse surgery, and you answered that all</p> <p>7 the complications are the same. Do you</p> <p>8 remember that?</p> <p>9 A. I do.</p> <p>10 Q. So you don't believe that mesh erosion,</p> <p>11 exposure, extrusion is a unique risk to pelvic</p> <p>12 organ prolapse surgery with mesh?</p> <p>13 A. Inasmuch as, you know, the mesh is a permanent</p> <p>14 synthetic material, and permanent synthetic</p> <p>15 materials are used for native tissue repairs,</p> <p>16 apical vault suspensions, that permanent</p> <p>17 sutures, which are akin to mesh in that</p> <p>18 they're nonabsorbable and are used in</p> <p>19 uterosacral suspensions and sacrospinous</p> <p>20 ligament fixations, those sutures -- and,</p> <p>21 actually, again, the sutures that are</p> <p>22 oftentimes used for the repairs of the</p> <p>23 anterior or posterior compartment, all of</p> <p>24 those sutures can erode, poke through the</p>

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<p>1 vaginal wall much like mesh can.</p> <p>2 Q. So you don't think that mesh erosion,</p> <p>3 exposure, extrusion is a unique risk of pelvic</p> <p>4 organ prolapse surgery with mesh; is that</p> <p>5 accurate?</p> <p>6 A. Inasmuch as patients can have exposures of,</p> <p>7 like, or permanent suture material, which is</p> <p>8 not unlike mesh, no, I don't feel it's a</p> <p>9 unique adverse event.</p> <p>10 Q. Earlier, defense counsel was asking you some</p> <p>11 questions about Exhibit No. 5 and pointed out</p> <p>12 that that adverse event report was reported by</p> <p>13 an attorney.</p> <p>14 A. Yes.</p> <p>15 Q. Do you know whether or not attorneys in all 50</p> <p>16 states in the United States have an ethical</p> <p>17 obligation to tell the truth and not</p> <p>18 misrepresent the facts of a particular case?</p> <p>19 A. I didn't sit for the Bar exam. I don't know</p> <p>20 what your code of ethics has you do or not do.</p> <p>21 Q. Do you know how many formal complaints have</p> <p>22 been filed with Ethicon and Johnson & Johnson</p> <p>23 regarding their pelvic mesh implants?</p> <p>24 A. I don't know.</p>	<p>1 so much related to the mesh themselves but to</p> <p>2 mismanagement by the patient's providers.</p> <p>3 Q. So you don't think that the percentage of</p> <p>4 patients who have filed a formal complaint to</p> <p>5 the company regarding the Prolift+M is a</p> <p>6 potential indicator of patient satisfaction or</p> <p>7 lack of patient satisfaction?</p> <p>8 MS. KATZ GERSTEL: Objection.</p> <p>9 A. I mean, I think we have good medical</p> <p>10 literature to support patient satisfaction</p> <p>11 with Prolift, at least specific on the</p> <p>12 original Prolift. I don't know that I would</p> <p>13 be able to opine about patient satisfaction</p> <p>14 just merely based on the number of complaints</p> <p>15 to the company.</p> <p>16 BY MR. FAES:</p> <p>17 Q. And earlier defense counsel was asking you</p> <p>18 questions about patients that you have</p> <p>19 implanted with Prolift+M and their follow-up</p> <p>20 care. Do you remember that?</p> <p>21 A. Yes.</p> <p>22 Q. Have you done any kind of formal analysis</p> <p>23 asking patients if they have gone and seen</p> <p>24 other doctors for problems or follow-up care</p>
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<p>1 Q. Do you think that would be information that</p> <p>2 would be useful in forming your opinions</p> <p>3 regarding whether or not the Ethicon pelvic</p> <p>4 mesh products are safe and effective?</p> <p>5 A. No.</p> <p>6 MS. KATZ GERSTEL: Objection.</p> <p>7 BY MR. FAES:</p> <p>8 Q. Do you know how many formal complaints have</p> <p>9 been filed against the company specifically</p> <p>10 with regard to the Prolift+M mesh?</p> <p>11 A. No.</p> <p>12 Q. You don't think that would be helpful</p> <p>13 information to have in forming your opinions</p> <p>14 regarding the safety and efficacy of the</p> <p>15 Prolift+M mesh?</p> <p>16 A. I think you have to evaluate every case</p> <p>17 individually for the merit behind the case. I</p> <p>18 mean, I think that people are entitled to</p> <p>19 complain or blame surgery on anything. It's</p> <p>20 one of the reasons why we spoke about recall</p> <p>21 bias in the report. I haven't had a chance to</p> <p>22 review a lot of cases in my time as an expert,</p> <p>23 but so far a lot of the cases that I've</p> <p>24 reviewed the purported complications are not</p>	<p>1 with their Prolift+M devices?</p> <p>2 A. I've not done a formal analysis, no.</p> <p>3 Q. So if another -- if one of your patients</p> <p>4 implanted with Prolift+M went to another</p> <p>5 doctor, and that doctor didn't tell you about</p> <p>6 it or was out of your area, you would have no</p> <p>7 way of knowing whether or not that patient</p> <p>8 went to another doctor for treatment of a</p> <p>9 complication with the Prolift+M, right?</p> <p>10 A. Well, luckily, I have a good relationship with</p> <p>11 the other three or four docs in the state that</p> <p>12 do what I do, and we keep an open line of</p> <p>13 communication. We sort of have this unwritten</p> <p>14 agreement to let each other know about each</p> <p>15 other's patients that perhaps don't follow up.</p> <p>16 It doesn't happen that often, and I can't</p> <p>17 remember the last time someone called me up</p> <p>18 about a patient that, you know, went to a</p> <p>19 different provider.</p> <p>20 Q. But if a patient with a Prolift+M seeks</p> <p>21 treatment outside of this network of three or</p> <p>22 four docs and doesn't tell you about it for</p> <p>23 problems with their Prolift+M, you would have</p> <p>24 no way of knowing about that, correct?</p>

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<p>1 A. I would have no way of knowing about that.</p> <p>2 Q. Doesn't it violate HIPAA rules for you doctors</p> <p>3 to be discussing complications that you've</p> <p>4 treated with each other's patients if you're</p> <p>5 referencing those patients by name?</p> <p>6 MS. KATZ GERSTEL: Objection.</p> <p>7 A. What we do typically is we ask the patient for</p> <p>8 their permission to contact the implanting</p> <p>9 physician prior to corresponding.</p> <p>10 BY MR. FAES:</p> <p>11 Q. So if a patient of yours that was implanted</p> <p>12 with a Prolift+M by you goes to another doctor</p> <p>13 for treatment of -- for treatment of a</p> <p>14 complication with the Prolift+M and doesn't</p> <p>15 give that other doctor consent to talk to you</p> <p>16 about it, you would also have no way of</p> <p>17 knowing about that, correct?</p> <p>18 A. That seems de facto, ipso facto, yeah.</p> <p>19 MR. FAES: I don't have any further</p> <p>20 questions for you at this time, Doctor. Thank</p> <p>21 you for your time.</p> <p>22 MS. KATZ GERSTEL: I just have one</p> <p>23 follow-up.</p> <p>24 RECROSS-EXAMINATION</p>	<p>1 I have.</p> <p>2 (The deponent will read and sign.)</p> <p>3 (The deposition concluded at 12:35</p> <p>4 p.m.)</p> <p>5</p> <p>6</p> <p>7</p> <p>8</p> <p>9</p> <p>10</p> <p>11</p> <p>12</p> <p>13</p> <p>14</p> <p>15</p> <p>16</p> <p>17</p> <p>18</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p>
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<p>1 BY MS. KATZ GERSTEL:</p> <p>2 Q. Doctor, could you please turn to page 13 of</p> <p>3 your report?</p> <p>4 A. 13.</p> <p>5 Q. Do you cite a paper by Barber on page 13 of</p> <p>6 your report?</p> <p>7 A. I did.</p> <p>8 Q. And did Barber -- well, strike that.</p> <p>9 Are uterosacral suspension and</p> <p>10 sacrospinous ligament fixation two non-mesh</p> <p>11 pelvic floor repairs for prolapse?</p> <p>12 A. They are.</p> <p>13 Q. And did Barber report on exposure rate for</p> <p>14 sutures after uterosacral ligament suspension</p> <p>15 and sacrospinous ligament fixation?</p> <p>16 A. He did.</p> <p>17 Q. And what did he report about suture exposure</p> <p>18 rates?</p> <p>19 MR. FAES: Object to form.</p> <p>20 A. So Matt Barber noted a 15.4 percent suture</p> <p>21 exposure rate after uterosacral suspension,</p> <p>22 and a 17.2 percent suture exposure rate after</p> <p>23 sacrospinous fixation.</p> <p>24 MS. KATZ GERSTEL: Thank you. That's all</p>	<p>1 I, TED ROTH, M.D., do hereby certify that the</p> <p>2 foregoing testimony taken on March 17, 2017, is</p> <p>3 true and accurate to the best of my knowledge and</p> <p>4 belief.</p> <p>5</p> <p>6</p> <p>7</p> <p>8 DATE TED ROTH, M.D.</p> <p>9</p> <p>10 At in said County of ,</p> <p>11 this day of , 2017 personally</p> <p>12 appeared TED ROTH, M.D., and he made oath to the</p> <p>13 truth of the foregoing answers by him subscribed.</p> <p>14 Before me, , a</p> <p>15 Notary Public</p> <p>16</p> <p>17</p> <p>18 My Commission Expires:</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p>

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<p>1 STATE OF MAINE</p> <p>2 I, Lynne M. Morrison, a Notary Public in</p> <p>3 and for the State of Maine, do hereby certify that</p> <p>4 pursuant to notice there came before me on March</p> <p>5 17, 2017, the following-named person to wit: TED</p> <p>6 ROTH, M.D., who was duly sworn to testify to the</p> <p>7 truth and nothing but the truth; that he was</p> <p>8 thereupon carefully examined upon his oath and his</p> <p>9 examination reduced to writing under my</p> <p>10 supervision; that this deposition is a true record</p> <p>11 of the testimony given by the witness.</p> <p>12 I further certify that I am neither</p> <p>13 attorney nor counsel for, nor related to, nor</p> <p>14 employed by any of the parties to the action in</p> <p>15 which this deposition is taken, and further, that</p> <p>16 I am not a relative or employee of any attorney or</p> <p>17 counsel employed by the parties hereto, or</p> <p>18 financially interested in this action.</p> <p>19 IN WITNESS WHEREOF, I have hereunto set my</p> <p>20 hand this 27th day of March, 2017.</p> <p>21</p> <p>22 Lynne M. Morrison</p> <p>23 My Commission Expires:</p> <p>24 April 4, 2019</p>	<p>1 LAWYER'S NOTES</p> <p>2 PAGE LINE</p> <p>3 _____</p> <p>4 _____</p> <p>5 _____</p> <p>6 _____</p> <p>7 _____</p> <p>8 _____</p> <p>9 _____</p> <p>10 _____</p> <p>11 _____</p> <p>12 _____</p> <p>13 _____</p> <p>14 _____</p> <p>15 _____</p> <p>16 _____</p> <p>17 _____</p> <p>18 _____</p> <p>19 _____</p> <p>20 _____</p> <p>21 _____</p> <p>22 _____</p> <p>23 _____</p> <p>24 _____</p>
<p>Page 103</p> <p>1 THE ORIGINAL DEPOSITION OF TED ROTH, M.D. SHOULD</p> <p>2 INCLUDE THE FOLLOWING CORRECTIONS:</p> <p>3</p> <p>4</p> <p>5</p> <p>6</p> <p>7</p> <p>8</p> <p>9</p> <p>10</p> <p>11</p> <p>12</p> <p>13</p> <p>14</p> <p>15</p> <p>16</p> <p>17</p> <p>18</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p> <p>TED ROTH, M.D.</p>	

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